

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 10/23/2017 7:42:02 PM
To: Joseph Conti [jconti@hartz.com]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Harty, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Harty, Thomas]
Subject: RE: TCVP Minutes

Hi Joe,

We will correct the notes to reflect the October 27th date for the white paper. Has Hartz been able to get in touch with the contract lab in South Africa about the new modifications to the in vivo animal study? Do you think you could give us an estimated date for submission of the revised study protocol on the 27th as well?

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]
Sent: Friday, October 20, 2017 9:13 AM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Subject: TCVP Minutes

I was traveling and just got back into office. I took a quick scan of minutes and did notice that you recorded that we would be filing white paper today. We had agreed on October 27 since I knew I would be traveling, please correct. I have forwarded minutes to team and will get back to you next week with any updates.

Joe Conti

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The Hartz Mountain Corporation

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 7/28/2017 7:23:41 PM
To: Joseph Conti [jconti@hartz.com]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]
Subject: RE: TCVP Follow-up

Hi Joe,

We have looked at Hartz' proposal for TCVP and in general, we like the proposal, but have some comments. Can we set up a call next week to discuss in more detail? Those on the call from EPA will be the following:

Wade Britton (HED)
Kelly Lowe (HED)
Mike Metzger (HED)
Danette Drew (HED)
Linda Taylor (HED)
Kirstin Rickard (HED)
Don Atwood (BEAD)
Steve Smearman (BEAD)
Melissa Grable (PRD)
Neil Anderson (PRD)
Myself

Here are several proposed times for a call:
Tues 8/1, 11 am-12 pm, or 3-4 pm
Thurs 8/3, 2-3 pm
Mon 8/7, 2-3 pm

Let us know when would work for Hartz.

Conference call information:

Personal Matters / Ex. 6

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]
Sent: Tuesday, July 25, 2017 1:22 PM
To: Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Keller, Kaitlin

<keller.kaitlin@epa.gov>; Nguyen, Khue <Nguyen.Khue@epa.gov>

Subject: TCVP Follow-up

I wanted to follow-up on the Hartz Mountain TCVP proposal which we filed with the Agency last week. We are working with outside laboratories to find a lab and finalize a protocol. It is our intention to follow the prescribed timeline but it is very important that we receive concurrence from EPA on our plan forward and receive an update on rolling back the proposed NRDC response.

Joe Conti
Sr Director Regulatory & Quality
Hartz Mountain Corporation

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The Hartz Mountain Corporation

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 7/6/2017 8:52:29 PM
To: jconti@hartz.com
CC: Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]
Subject: RE: TCVP: meeting request
Attachments: TCVP Risk Summary for Pet Uses.docx

Hi Joe,

To facilitate the discussion for TCVP next Tuesday, I went ahead and put together a short summary of the risk picture for the pet uses. There is no new information here, but it may be in a more digestible format.

You mentioned during a previous phone conversation that there were open lit data for pet collars that we might have overlooked? Would it be possible to send us a reference list of this open lit data?

It is possible that we might have already looked at some of these studies, even if they did not contain enough information for risk assessment.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Nguyen, Khue
Sent: Thursday, June 29, 2017 11:43 AM
To: 'jconti@hartz.com' <jconti@hartz.com>
Cc: Grable, Melissa <Grable.Melissa@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>
Subject: RE: TCVP: meeting request

Hi Joe,

Minor correction: Kelly Lowe and Danette Drew will not be in attendance for the teleconference—they will be out on vacation.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248

Nguyen.khue@epa.gov

From: Nguyen, Khue
Sent: Thursday, June 29, 2017 11:27 AM
To: 'jconti@hartz.com' <jconti@hartz.com>
Cc: Grable, Melissa <Grable.Melissa@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>
Subject: RE: TCVP: meeting request

Hi Joe,

Thanks for your call this morning. We are confirmed for a teleconference on Tuesday 7/11 from 3-4 pm.

As I mentioned, expected attendees for the teleconference from our end would be myself, Melissa Grable (PRD), Neil Anderson (PRD), Wade Britton (HED), Mike Metzger (HED), Danette Drew (HED), Linda Taylor (HED), and Kelly Lowe (HED).

Please use the following teleconferencing info:

Personal Matters / Ex. 6

We are interested in learning about the contents of the memo which Hartz said it would submit in the near future. We can also give you a heads up in terms of where we stand for TCVP and where we are leaning for pet collars specifically.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Nguyen, Khue
Sent: Tuesday, June 27, 2017 12:25 PM
To: 'jconti@hartz.com' <jconti@hartz.com>
Cc: Grable, Melissa <Grable.Melissa@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>
Subject: TCVP: meeting request

Hi Joe,

After our conversation this morning, I discussed TCVP with my management and we think the earlier we can get together to discuss the uncertainty regarding the composition of the pet collars (% liquid vs. dust), the better. You mentioned this morning that you had additional information on the composition of the pet collars that you intended to submit as part of a memo. Would you be willing to schedule a teleconference with EPA (including our occupational exposure folks) in early/mid-July and discuss what sort of information will be in Hartz's memo and begin to scope out whether this information will impact the risk picture for pet collars? For us, the content and quality of the information has an impact.

For the teleconference, here are some proposed times:
Thurs 7/6, 1-2 pm (fewer EPA folks can attend this time, so this is least preferred)
Mon 7/10, 11:30 am-12:30 pm or 1-2 pm
Tues 7/11, 2-3 pm or 3-4 pm

Expected attendees for the teleconference would be myself, Melissa Grable (PRD), Neil Anderson (PRD), Wade Britton (HED), Mike Metzger (HED), Danette Drew (HED), Linda Taylor (HED), and Kelly Lowe (HED).

We still think it would be helpful to meet formally in early August to discuss the path forward for TCVP, after EPA has had a chance to review the additional information in your memo. Some proposed times for the August meeting are below:

Thursday 8/3, 1-2 pm

Monday 8/7, 1-2 pm, or 2-3 pm

Tuesday 8/8, 11-12 pm

An agenda and a list of attendees from EPA (for the August meeting) will follow after we have determined the meeting time. We are not sure that Bayer will attend the August meeting.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Nguyen, Khue
Sent: Thursday, June 22, 2017 4:43 PM
To: 'Doug Spilker' <doug.spilker@bayer.com>; 'lhemsarth@hartz.com' <lhemsarth@hartz.com>
Cc: Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>
Subject: TCVP: meeting request

Hi all,

We would like to meet with TCVP technical registrants and discuss the risks, the path forward for TCVP (in relation to the other organophosphate pesticides), and the pet uses for TCVP. Specifically, we want to discuss the pet collar use and how to move forward to address risks for pet collars.

Here are some proposed times when the team is available:

Thursday 7/6 from 2-3 pm; or from 3-4 pm

Wednesday 7/12 from 11 am-12 pm; or from 1-2 pm

Unfortunately, there are limited days when most of us are available—folks tend to be on vacation around July 4th. I am out of the office for 2 weeks in July as well. We appreciate your flexibility.

We encourage registrants to attend in person when they can, but we will open a teleconference line if you prefer to call in.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1

Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 7/6/2017 7:22:37 PM
To: Doug Spilker [doug.spilker@bayer.com]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]
Subject: RE: TCVP Follow-up

Hi Doug,

Maybe it is a copying error, but the right hand side of the text on the first page was cut off. Can you resend?

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Thursday, July 06, 2017 2:58 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Cc: Robert Zolynas <robert.zolynas@bayer.com>; Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Biggio, Patricia <biggio.patricia@epa.gov>
Subject: RE: TCVP Follow-up

Dear Ms. Nguyen,

Thank you again for setting up the discussion this morning. We as well thought it was a fruitful discussion.

As we discussed, Bayer requests you post the attached letter to the Tetrachlorvinphos (TCVP) Docket ID: EPA-HQ-OPP-2008-0316. At an appropriate time, Bayer Animal Health would be very interested in sharing our knowledge regarding the use of TCVP-containing products on food animals and their surroundings. I have already discussed this with our technical staff, and we would suggest Bayer prepare a presentation and other information to apprise the Agency of how these products are used and their value, and would certainly welcome USDA's involvement. We should consider this later this year.

If there are any questions concerning this response, please contact me by telephone (913-268-2751) or e-mail (doug.spilker@bayer.com).

Best regards,

Doug

Douglas A. Spilker, Ph.D.

Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [<mailto:Nguyen.Khue@epa.gov>]
Sent: Thursday, July 06, 2017 12:26 PM
To: Doug Spilker
Cc: Robert Zolynas; Anderson, Neil; Grable, Melissa; Biggio, Patricia
Subject: RE: TCVP Follow-up

Hi Doug,

Thanks for chatting with us. We thought it was a good conversation. Attached is the attendance sheet for the teleconference.

In case you can't read my chicken scratch handwriting, the attendees from EPA are:

Yu-Ting Guilaran
Charles "Billy" Smith
Neil Anderson
Melissa Grable
Patricia Biggio
And myself

As discussed, we look forward to receiving the memorandum addressing the 10X SF which is intended to be posted to the TCVP reg review docket and a separate request for voluntary cancellation of the pet collar products. EPA is interested in additional information on the livestock (poultry, cattle, swine) uses of TCVP and we can get together to discuss those uses in the near future. We already sent some questions about these uses to USDA, so it might be possible to coordinate with USDA on this.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]
Sent: Thursday, July 06, 2017 12:55 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>

Cc: Robert Zolynas <robert.zolynas@bayer.com>

Subject: TCVP Follow-up

Hi Khue,

Thanks again for setting up the teleconference and getting the right people there. I thought it went well.

One of the action items from the call was for me to check to be sure that we did not have any other TCVP-containing pet products besides the two pet collars (EPA Reg. Nos. 11556-164 and -165).

I can confirm that the above listed are the only TCVP-containing pet products registered by Bayer.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA

Tel: +1 913 268 2751

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E-mail: doug.spilker@bayer.com

Web: <http://www.bayer.com>

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Message

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Sent: 7/6/2017 7:20:28 PM
To: Doug Spilker [doug.spilker@bayer.com]
CC: Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]
Subject: RE: TCVP Follow-up

Hi Doug,

There was no one from BEAD present. Neil was referring to our interest in more information on the livestock uses of TCVP. He said members of the team from BEAD did some research on poultry and cattle uses earlier this summer and reached out to USDA with questions—but this type of info is of primary interest for BEAD and PRD. It will help us determine which uses are important, how some of the products are used, and how the labels might be updated for additional clarification.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Thursday, July 06, 2017 3:01 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Subject: RE: TCVP Follow-up

Hi Khue,
Thank you for the follow-up. We will request cancellation of the two pet collars no later than by next week. I am awaiting a reply from the Registration Division on the best way to quickly cancel the registrations.

Regarding the list of attendees, I thought I heard someone identify themselves from BEAD. Did I misunderstand?

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs

P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [<mailto:Nguyen.Khue@epa.gov>]
Sent: Thursday, July 06, 2017 12:26 PM
To: Doug Spilker
Cc: Robert Zolynas; Anderson, Neil; Grable, Melissa; Biggio, Patricia
Subject: RE: TCVP Follow-up

Hi Doug,

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In case you can't read my chicken scratch handwriting, the attendees from EPA are:

Yu-Ting Guilaran
Charles "Billy" Smith
Neil Anderson
Melissa Grable
Patricia Biggio
And myself

As discussed, we look forward to receiving the memorandum addressing the 10X SF which is intended to be posted to the TCVP reg review docket and a separate request for voluntary cancellation of the pet collar products. EPA is interested in additional information on the livestock (poultry, cattle, swine) uses of TCVP and we can get together to discuss those uses in the near future. We already sent some questions about these uses to USDA, so it might be possible to coordinate with USDA on this.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]
Sent: Thursday, July 06, 2017 12:55 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Cc: Robert Zolynas <robert.zolynas@bayer.com>
Subject: TCVP Follow-up

Hi Khue,
Thanks again for setting up the teleconference and getting the right people there. I thought it went well.

One of the action items from the call was for me to check to be sure that we did not have any other TCVP-containing pet products besides the two pet collars (EPA Reg. Nos. 11556-164 and -165).

I can confirm that the above listed are the only TCVP-containing pet products registered by Bayer.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com

Web: <http://www.bayer.com>

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Message

From: Grable, Melissa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=017278065A7C4CD68F85ECAFF5596788-GRABLE, MELISSA]
Sent: 8/24/2017 5:36:17 PM
To: Joseph Conti [jconti@hartz.com]; Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc88-Nguyen, Khue]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]
CC: Dr. Jeffrey Driver [Personal Matters / Ex. 6]; John Ross [jhross@surewest.net]; Lance Hemsarth [lhemsarth@hartz.com]; Keith Goldman [kgoldman@hartz.com]; Anna McGrath [amcgrath@hartz.com]
Subject: RE: Hartz Mountain - TCVP

Joe,

Thank you for providing the test outline for the animal collar testing. We are beginning to review it now, but have not had enough time to review it before our meeting this afternoon. We can still meet to discuss any initial thoughts/feedback we might have, as well as begin discussions on the dust/powder pet products. The call in number provided is correct.

Melissa

Melissa Grable, Team Leader
U.S. Environmental Protection Agency
OCSPP/OPP/PRD/RMIB 1
grable.melissa@epa.gov
(703) 308-3953

From: Joseph Conti [mailto:jconti@hartz.com]
Sent: Thursday, August 24, 2017 11:30 AM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>
Cc: Dr. Jeffrey Driver [Personal Matters / Ex. 6]; John Ross <jhross@surewest.net>; Lance Hemsarth <lhemsarth@hartz.com>; Keith Goldman <kgoldman@hartz.com>; Anna McGrath <amcgrath@hartz.com>
Subject: Hartz Mountain - TCVP

I have attached a test outline for the on animal collar testing. This is an outline and we are continuing to work with Clinvet to finalize a protocol, which will then be submitted for your review. Please advise and forward agenda for meeting today.

Joe Conti

Please confirm call-in number will be: **Personal Matters / Ex. 6**

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The Hartz Mountain Corporation

Message

From: Joseph Conti [jconti@hartz.com]
Sent: 8/24/2017 3:30:17 PM
To: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]
CC: Dr. Jeffrey Driver [DriverJH@comcast.net]; John Ross [jhross@surewest.net]; Lance Hemsarh [lhemsarh@hartz.com]; Keith Goldman [kgoldman@hartz.com]; Anna McGrath [amcgrath@hartz.com]
Subject: Hartz Mountain - TCVP
Attachments: ClinVet2806 CG264-CV17-061_First Test_Outline_Rev 23 Aug 2017_AV (1) (1) (1).docx

I have attached a test outline for the on animal collar testing. This is an outline and we are continuing to work with Clinvet to finalize a protocol, which will then be submitted for your review. Please advise and forward agenda for meeting today.

Joe Conti

Please confirm call-in number will be; **Personal Matters / Ex. 6**

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Sent: 8/23/2017 8:13:25 PM
To: Joseph Conti [jconti@hartz.com]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Britton, Wade [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c4124ab767b4c96b4b436bd02bccfbb-Wade T Britton]; Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]
Subject: RE: Hartz Mountain TCVP Protocol

Joe,

I have not yet seen the animal protocol that Khue mentioned in her email of last week. When will this protocol be available for EPA to review? In addition, tomorrow we will need to begin discussions on the dust/powder pet products, in addition to continuing our conversations on the pet collars.

Thanks,
Melissa

Melissa Grable, Team Leader
U.S. Environmental Protection Agency
OCSPP/OPP/PRD/RMIB 1
grable.melissa@epa.gov
(703) 308-3953

From: Nguyen, Khue
Sent: Wednesday, August 16, 2017 5:16 PM
To: Joseph Conti <jconti@hartz.com>
Cc: Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Britton, Wade <Britton.Wade@epa.gov>
Subject: RE: Hartz Mountain TCVP Protocol

Hi Joe,

When should we expect the animal protocol? Would you be able to send it this week? To fully evaluate the wipe and weigh study, we really need insight into the animal study. It would make for a more productive conversation next week.

By the way, I will be out of the office starting tomorrow and will be back on the 28th. Please copy Neil and Melissa on all TCVP correspondence while I am out.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [<mailto:jconti@hartz.com>]
Sent: Tuesday, August 15, 2017 3:05 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Subject: Re: Hartz Mountain TCVP Protocol

No. We are working on an on animal protocol with lab and hoe to have protocol to discuss next week

On Tue, Aug 15, 2017 at 3:02 PM Nguyen, Khue <Nguyen.Khue@epa.gov> wrote:

Hi Joe,

Is the attached proposed wipe and weigh study the only study that Hartz intends to conduct to address issues associated with the TCVP pet collar risk assessment?

Thanks,

Khue Nguyen

Chemical Review Manager

Risk Management and Implementation Branch 1

Pesticide Re-evaluation Division

Office of Pesticide Programs, EPA

703-347-0248

Nguyen.khue@epa.gov

From: Joseph Conti [<mailto:jconti@hartz.com>]
Sent: Tuesday, August 15, 2017 2:50 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Subject: Re: Hartz Mountain TCVP Protocol

I am on vacation return Monday wanted to make sure you received protocol so we can discuss next week. JoeConti

On Tue, Aug 15, 2017 at 2:47 PM Nguyen, Khue <Nguyen.Khue@epa.gov> wrote:

Thanks Joe, I just sent this to the HED team for review.

Khue Nguyen

Chemical Review Manager

Risk Management and Implementation Branch 1

Pesticide Re-evaluation Division

Office of Pesticide Programs, EPA

703-347-0248

Nguyen.khue@epa.gov

From: Joe Conti [mailto:jconti@hartz.com] **Personal Matters / Ex. 6**

Sent: Tuesday, August 15, 2017 2:35 PM

To: Nguyen, Khue <Nguyen.Khue@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>

Cc: Joe Conti <jconti@hartz.com>

Subject: Hartz Mountain TCVP Protocol

Attached is the proposed protocol we discussed for evaluation and comment. We are continuing to work on the on animal protocol with the laboratory. I am on vacation and sending from my personal email address, please confirm receipt of the document.

Joe Conti

Sr. Director Regulatory & Quality

Hartz Mountain Cotproation

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Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 7/27/2017 10:18:59 PM
To: Doug Spilker [doug.spilker@bayer.com]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]
Subject: RE: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Hi Doug,

I just checked regulations.gov and the document has been posted (see image below). Usually it takes the docket staff about 2 weeks to process this sort of request.

regulations.gov
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EPA-HQ-OPP-2008-0316

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Tetrachlorvinphos (Gardona): Registration Review Docket Opening

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Docket ID: EPA-HQ-OPP-2008-0316 **Agency:** Environmental Protection Agency (EPA)

Summary:
For further information contact: James Parker (703) 305-0469 Mail code (7506P)

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Comment Submitted by Douglas Spilker Ph.D., Manager, EPA Regulatory Affairs, Bayer Animal Health
See Attached
Public Submission | Posted: 6/27/2017 | ID: EPA-HQ-OPP-2008-0316-0075
Comment Period Closed

Comment submitted by Douglas A. Spilker, Ph.D., Bayer HealthCare
See attached file(s)
Public Submission | Posted: 12/14/2016 | ID: EPA-HQ-OPP-2008-0316-0091
Comment Period Closed
May 11, 2016 11:59 PM ET

Comment submitted by Natural Resources Defense Council (NRDC)
Attached please find comments from The Natural Resources Defense Council (NRDC). We appreciate EPA's review and consideration of the peer-reviewed scientific literature as part.
Public Submission | Posted: 05/12/2016 | ID: EPA-HQ-OPP-2008-0316-0049
Comment Period Closed
May 11, 2016 11:59 PM ET

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248

ED_002155A_00000688-00001

Nguyen.khue@epa.gov

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]
Sent: Thursday, July 27, 2017 7:27 AM
To: Grable, Melissa <Grable.Melissa@epa.gov>
Cc: Nguyen, Khue <Nguyen.Khue@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>
Subject: Re: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Melissa, Thank you.

Douglas A. Spilker, Ph. D.
Bayer Animal Health
This message may be brief since it was sent from my iPhone (816-506-3102). Office #913-268-2751.

On Jul 26, 2017, at 5:14 PM, Grable, Melissa <Grable.Melissa@epa.gov> wrote:

<image002.gif>
Hi Doug,

Khue is back in the office tomorrow. We will checking into this and get back to you.

Thanks,
Melissa

Melissa Grable, Team Leader
U.S. Environmental Protection Agency
OCSPP/OPP/PRD/RMIB 1
grable.melissa@epa.gov
(703) 308-3953

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]
Sent: Wednesday, July 26, 2017 2:54 PM
To: Grable, Melissa <Grable.Melissa@epa.gov>
Subject: FW: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Hi Melissa,
I see that Khue is on vacation. Would you happen to know the status of the aforementioned letter being posted to the TCVP docket? I assume it would be posted in the comment section.

Best regards,
Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA

Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Doug Spilker
Sent: Wednesday, July 26, 2017 1:29 PM
To: Nguyen, Khue (Nguyen.Khue@epa.gov)
Subject: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Hi Khue,

I looked at the docket again today, and do not yet see our letter posted. If you know when it might be posted, we would appreciate an alert.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Doug Spilker
Sent: Thursday, July 06, 2017 1:58 PM
To: 'Nguyen, Khue'
Cc: Robert Zolynas; Anderson, Neil; Grable, Melissa; Biggio, Patricia
Subject: RE: TCVP Follow-up

Dear Ms. Nguyen,

Thank you again for setting up the discussion this morning. We as well thought it was a fruitful discussion.

As we discussed, Bayer requests you post the attached letter to the Tetrachlorvinphos (TCVP) Docket ID: EPA-HQ-OPP-2008-0316. At an appropriate time, Bayer Animal Health would be very interested in sharing our knowledge regarding the use of TCVP-containing products on food animals and their surroundings. I have already discussed this with our technical staff, and we would suggest Bayer prepare a presentation and other

information to apprise the Agency of how these products are used and their value, and would certainly welcome USDA's involvement. We should consider this later this year.

If there are any questions concerning this response, please contact me by telephone (913-268-2751) or e-mail (doug.spilker@bayer.com).

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
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Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [<mailto:Nguyen.Khue@epa.gov>]
Sent: Thursday, July 06, 2017 12:26 PM
To: Doug Spilker
Cc: Robert Zolynas; Anderson, Neil; Grable, Melissa; Biggio, Patricia
Subject: RE: TCVP Follow-up

Hi Doug,

Thanks for chatting with us. We thought it was a good conversation. Attached is the attendance sheet for the teleconference.

In case you can't read my chicken scratch handwriting, the attendees from EPA are:

Yu-Ting Guilaran
Charles "Billy" Smith
Neil Anderson
Melissa Grable
Patricia Biggio
And myself

As discussed, we look forward to receiving the memorandum addressing the 10X SF which is intended to be posted to the TCVP reg review docket and a separate request for voluntary cancellation of the pet collar products. EPA is interested in additional information on the livestock (poultry, cattle, swine) uses of TCVP and we can get together to discuss those uses in the near future. We already sent some questions about these uses to USDA, so it might be possible to coordinate with USDA on this.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]
Sent: Thursday, July 06, 2017 12:55 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Cc: Robert Zolynas <robert.zolynas@bayer.com>
Subject: TCVP Follow-up

Hi Khue,
Thanks again for setting up the teleconference and getting the right people there. I thought it went well.

One of the action items from the call was for me to check to be sure that we did not have any other TCVP-containing pet products besides the two pet collars (EPA Reg. Nos. 11556-164 and -165).

I can confirm that the above listed are the only TCVP-containing pet products registered by Bayer.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
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Message

From: Grable, Melissa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=017278065A7C4CD68F85ECAFF5596788-GRABLE, MELISSA]
Sent: 7/26/2017 10:14:32 PM
To: Doug Spilker [doug.spilker@bayer.com]
CC: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]
Subject: RE: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Hi Doug,

Khue is back in the office tomorrow. We will checking into this and get back to you.

Thanks,
Melissa

Melissa Grable, Team Leader
U.S. Environmental Protection Agency
OCSPP/OPP/PRD/RMIB 1
grable.melissa@epa.gov
(703) 308-3953

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Wednesday, July 26, 2017 2:54 PM
To: Grable, Melissa <Grable.Melissa@epa.gov>
Subject: FW: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Hi Melissa,
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Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
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Tel: +1 913 268 2751
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E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

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Manager, EPA Regulatory Affairs

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Cc: Robert Zolynas; Anderson, Neil; Grable, Melissa; Biggio, Patricia
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Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

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Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248

Nguyen.khue@epa.gov

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Sent: Thursday, July 06, 2017 12:55 PM
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Cc: Robert Zolynas <robert.zolynas@bayer.com>
Subject: TCVP Follow-up

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Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 8/15/2017 7:02:06 PM
To: Joseph Conti [jconti@hartz.com]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Britton, Wade [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c4124ab767b4c96b4b436bd02bccfbb-Wade T Britton]
Subject: RE: Hartz Mountain TCVP Protocol

Hi Joe,

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Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]
Sent: Tuesday, August 15, 2017 2:50 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Subject: Re: Hartz Mountain TCVP Protocol

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On Tue, Aug 15, 2017 at 2:47 PM Nguyen, Khue <Nguyen.Khue@epa.gov> wrote:

Thanks Joe, I just sent this to the HED team for review.

Khue Nguyen

Chemical Review Manager

Risk Management and Implementation Branch 1

Pesticide Re-evaluation Division

Office of Pesticide Programs, EPA

703-347-0248

Nguyen.khue@epa.gov

From: Joe Conti [mailto:Personal Matters / Ex. 6]
Sent: Tuesday, August 15, 2017 2:35 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>
Cc: Joe Conti <jconti@hartz.com>
Subject: Hartz Mountain TCVP Protocol

Attached is the proposed protocol we discussed for evaluation and comment. We are continuing to work on the on animal protocol with the laboratory. I am on vacation and sending from my personal email address, please confirm receipt of the document.

Joe Conti

Sr. Director Regulatory & Quality

Hartz Mountain Cotproation

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The Hartz Mountain Corporation

Message

From: Joe Conti [Personal Matters / Ex. 6]
Sent: 8/15/2017 6:35:08 PM
To: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]
CC: Joe Conti [jconti@hartz.com]
Subject: Hartz Mountain TCVP Protocol
Attachments: TCVP Bloom Study for Flea Collar 8-11-17 (3).doc

Attached is the proposed protocol we discussed for evaluation and comment. We are continuing to work on the on animal protocol with the laboratory. I am on vacation and sending from my personal email address, please confirm receipt of the document.

Joe Conti
Sr. Director Regulatory & Quality
Hartz Mountain Cotproation

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 8/30/2017 10:54:08 PM
To: Joseph Conti [jconti@hartz.com]
CC: Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]
Subject: TCVP follow up
Attachments: Meeting notes from meeting with Hartz_08_29_17_revised.docx

Hi Joe,

I am back from vacation. Attached please find the notes from the TCVP teleconference last week (Melissa put these together). Please review and let us know if we mischaracterized anything.

We want to set up a follow up discussion to talk about all the protocols (including the expected analytical protocol) and discuss timing for study initiation. Here are some proposed times during the week of September 11th:

Mon 9/11, 11 am-12 pm; or 1-2 pm
Wed 9/13, 10-11 am
Thurs 9/14, 2-3 pm

Folks likely in attendance from our end will be: Neil Anderson (PRD), Melissa Grable (PRD), Trish Biggio (PRD), Wade Britton (HED), Kelly Lowe (HED), Kristin Rickard (HED), Laura Bacon (HED), Danette Drew (HED), Mike Metzger (HED), and myself

Let me know when works best.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]
Sent: Thursday, August 24, 2017 11:30 AM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>
Cc: Dr. Jeffrey Driver [Personal Matters / Ex. 6]; John Ross <jhross@surewest.net>; Lance Hemsarth <lhemsarth@hartz.com>; Keith Goldman <kgoldman@hartz.com>; Anna McGrath <amcgrath@hartz.com>
Subject: Hartz Mountain - TCVP

I have attached a test outline for the on animal collar testing. This is an outline and we are continuing to work with Clinvet to finalize a protocol, which will then be submitted for your review. Please advise and forward agenda for meeting today.

Joe Conti

Please confirm call-in number will be; **Personal Matters / Ex. 6**

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The Hartz Mountain Corporation

TCVP Follow-up Data Development Discussion with Hartz – August 24, 2017
3:00 – 4:00 p.m.

Meeting Attendees:

EPA:

Wade Britton, HED
Jeff Dawson, HED
Kelly Lowe, HED
Kristin Rickard, HED
Laura Bacon, HED
Melissa Grable, PRD
Patricia Biggio, PRD

On-phone:

Jeff Driver
John Ross
Lance Hemsarh
Keith Goldman
Joe Conti

Meeting Notes:

Two draft protocols were submitted by Hartz for EPA's initial impressions:

- 1) First draft protocol- GLP Wipe and Weigh Protocol for the HUG Flea and Tick Collar
- 2) Second draft protocol- Kinetic Study of the Release of TCVP from a Collar Formulation on Dogs

EPA asked for clarification between these protocols because the two protocols seemed to be similar and addressing the same question.

Hartz stated that the first draft protocol provided (for the Wipe and Weigh Study), in combination with analysis of existing data (bloom data from 1980), could be done in-house and quickly, and this study is to address the liquid vs. solid ratio question. The study may also be used to address the hybrid transfer coefficient (TC). The protocol for the second study is to address the rate of release and is an *in vivo* study. This study will address the amount released over time and the amount still available in the collar. Hartz stated that 60% is released and 40% is left in the collar. Hartz believes that the *in vivo* study will confirm the 1980 bloom data.

Just prior to the meeting Hartz provided two photos of samples, and stated that this was to help address the liquid vs. solid question. The photos were of samples created in the lab, which consisted of the active ingredient (TCVP) in a solid form combined with the liquid plasticizer. This combination creates a paste dispersion or a viscous liquid. Hartz responded that the collar is made up of the two substances in a 1:2 ratio (solid:liquid) on a nominal basis. Hartz stated that this ratio does not change.

EPA asked if TCVP is always released as a solid. Hartz replied that yes, it is always a solid, but not 100% solid, because the two compounds are "intimately" intertwined, and both the liquid and solid are released from the collar simultaneously. The physical character is a crystalline material bonded with a liquid. Based on this discussion, EPA stated that it would be interesting to know which is the most appropriate TC and why. Hartz responded that it will either be a liquid or a liquid hybrid.

EPA stated that it was unclear from reading the Wipe and Weigh protocol that Hartz would be analyzing for both the solid TCVP and the liquid plasticizer. Hartz stated that they would be providing another protocol with the chemical analysis, since the chemical analysis for both protocols will be the same.

EPA also asked about distribution of the product across the animal. Hartz replied that the liquid aspect of what is released from the collar, in combination with the oils in the dog's coat, help to facilitate the movement the product across the dog. They noted that they have efficacy data to show that fleas and ticks are controlled across the animal. If the product was not completely covering the animal, there would be evidence of fleas and ticks on parts of the animal where the product had not yet reached, which is not what was shown by the efficacy data.

Hartz indicated that the data from these studies will be mostly confirmatory to address and confirm the form and relative amounts of chemical released.

EPA also asked if Hartz was planning on doing a mannequin hand study to address the TC. Hartz said that they were not planning to, but that fur clippings might also address this question. They said that they would consider this and get back to EPA.

Hartz asked if EPA wanted cats included in the *in vivo* study. If so, they would reduce the number of animals tested from 6 to 4 within each group. Hartz raised the issue of higher exposure with a smaller sized pet. EPA stated that it would prefer a greater number of animals tested, even if that meant only one species was tested. EPA clarified that they would be fine with just the dog study, but that Hartz could decide to include cats. EPA further noted that according to the protocol, the study length is 210 days; however, the Agency has previously stated, and again stated, that it would prefer a month long study. If Hartz chooses to conduct the study for the full 210 days, EPA expects to receive a report for the first 30 days of the study, and the protocol should be amended to include the report at 30 days.

EPA indicated that the protocols needed to be clearer in terms of what the end result will be and what questions they are meant to answer. EPA suggested that something be submitted to summarize the protocols being proposed and the information that will be provided. Hartz stated that they would provide a white paper with the research questions and what they are trying to address, as well as the amended first protocol (Wipe and Weigh) and the analytical protocol no later than September 6th. They will also provide an update on the availability of the *in vivo* protocol at that time.

EPA stated that it would not be providing the Proposed Interim Decision (PID) at the end of September, but it instead would provide an update stating that additional data was being generated by the registrant to address uncertainties identified in the risk assessment. Hartz stated that they wanted to review the update before it was made public. In addition, they wanted to ensure that the supplier was identified as the Task Force and not specifically Hartz. EPA stated that it would check on these two items and respond back to Hartz.

Next Steps:

- Hartz will provide a white paper to EPA that addresses the existing and proposed data.
 - Information addressed in the white paper should include what Hartz believes on the following topics:
 - What question(s) each study will address, and if data may be considered refinement, confirmation or new information.

- How the proposed data will be considered within the context of existing data (*e.g.*, bloom study, EPA's residential SOPs).
- After receiving the updated draft protocols, EPA will consider these in tandem with the white paper and additional information from Hartz, and work with Hartz to determine a schedule for study initiation and submission.

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 8/11/2017 2:25:20 PM
To: Joseph Conti [jconti@hartz.com]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]
Subject: RE: notes from TCVP discussion

The only time we are available on August 24th is from 3-4 pm. Will that work?

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]
Sent: Friday, August 11, 2017 10:16 AM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Cc: Anderson, Neil <Anderson.Neil@epa.gov>; Britton, Wade <Britton.Wade@epa.gov>; Drew, Danette <Drew.Danette@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Lowe, Kelly <Lowe.Kelly@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Rickard, Kristin <Rickard.Kristin@epa.gov>
Subject: Re: notes from TCVP discussion

These times are not good since Dr Driver and ROss are both traveling and making presentations at conferences. Can we make it Thursday Aug 24. This will also give EPA time to review and comment on the short t protocols I will be sending in next week. JoeConti

On Thu, Aug 10, 2017 at 5:47 PM Nguyen, Khue <Nguyen.Khue@epa.gov> wrote:

Hi Joe,

Attached are the notes and sign in sheet from Monday's discussion for TCVP. Please review and let me know if we have mischaracterized anything.

Also, as discussed on the phone this afternoon, here are some possible times for a follow up teleconference:

Mon 8/21, 1-2 pm

Tues 8/22, 11 am-12 pm

Wed 8/23 11 am-12 pm; or 3-4 pm

Call in info for the teleconference:

Personal Matters / Ex. 6

Folks attending from our end: Melissa Grable (PRD), Neil Anderson (PRD), Wade Britton (HED), Kelly Lowe (HED), Kristen Rickard (HED).

I will be out of the office from 8/17 to 8/25. **Please be sure to copy Neil and Melissa on all TCVP correspondence.** Melissa can lead the follow up teleconference in my absence.

If we receive Hartz' protocol by the 16th next week (as you indicated), we will try to look at it as soon as possible in order to have a more productive discussion the week of the 21st.

Thanks,

Khue Nguyen

Chemical Review Manager

Risk Management and Implementation Branch 1

Pesticide Re-evaluation Division

Office of Pesticide Programs, EPA

703-347-0248

Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]

Sent: Monday, August 07, 2017 11:27 AM

To: Nguyen, Khue <Nguyen.Khue@epa.gov>

Cc: Dr. Jeffrey Driver <jdriver@hartz.com> **Personal Matters / Ex. 6**; John Ross <jhross@surewest.net>; Lance Hemsarth <lhemsarth@hartz.com>; Keith Goldman <kgoldman@hartz.com>; Yasushi Takeda <ytakeda@hartz.com>

Subject: Proposal/Time Lines

Attached is a proposal and timeline for discussion today. We understand that EPA has requested the meeting to comment on our July 18 submission and the attached testing and timelines may be altered based on our call.

Joe

This e-mail contains confidential and privileged information. If you think you received this e-mail in error, please advise sender by return e-mail, and then delete this e-mail message immediately.

The Hartz Mountain Corporation

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The Hartz Mountain Corporation

Message

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Sent: 8/7/2017 3:40:33 PM
To: Joseph Conti [jconti@hartz.com]
CC: Dr. Jeffrey Driver [Personal Matters / Ex. 6] John Ross [jhross@surewest.net]; Lance Hemsarth [lhemsarth@hartz.com]; Keith Goldman [kgoldman@hartz.com]; Yasushi Takeda [ytakeda@hartz.com]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Britton, Wade [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c4124ab767b4c96b4b436bd02bccfbb-Wade T Britton]
Subject: RE: Proposal/Time Lines
Attachments: HED response to Hartz letter_7.31.17.docx

Hi Joe,

Attached please find preliminary comments from EPA on Hartz' data development proposal for TCVP. We would like to focus today's discussion on the data development.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]
Sent: Monday, August 07, 2017 11:27 AM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Cc: Dr. Jeffrey Driver [Personal Matters / Ex. 6] John Ross <jhross@surewest.net>; Lance Hemsarth <lhemsarth@hartz.com>; Keith Goldman <kgoldman@hartz.com>; Yasushi Takeda <ytakeda@hartz.com>
Subject: Proposal/Time Lines

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Joe

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The Hartz Mountain Corporation

HED Response to Hartz Follow-up Letter to July 11th Conference Call

As follow up to the July 11, 2017 conference call between Hartz and EPA, Hartz submitted a letter itemizing existing data and summarizing proposed data development to further inform and refine EPA's recent exposure and risk analyses for TCVP-based pet collars. Below are HED's responses to those items.

Item 1: Hartz proposal that contact time/duration of young children measured by NERL in 2 published studies (Beamer et al., 2008; Au Yeung et al., 2007¹) be utilized in the pet exposure calculations.

- While HED acknowledges that the two publications provided by Hartz provide information on exposure time with animals, HED notes several concerns with the use of those studies:
 - The Au Yeung et al., 2007 publication was aimed primarily at collecting hand contact frequencies for young children in the outdoor environment. Only 9 children spent 15 minutes or more in the indoor environment.
 - For both publications, the population solicited and included in the analysis was not specifically chosen because they owned pets. It does not appear from the study method description that all families owned pets and/or how many of the participating families owned pets.
 - For both publications, contact with “animals” is not explicitly described as far as what type of animals were contacted. This is of particular concern with the Beamer, 2008 publication since the analysis focused on children of farmworkers, and could have included contact with farm animals. It is unclear if the contact frequency represents exposure to dogs/cats (the animals of concern related to pet collars), or other types of animals.
 - The current exposure duration recommended in HED's Residential SOPs (1 hr) is based on information collected in 24-hour diaries of families who owned pets [Tsang and Klepeis, 1996 (as presented in 1997 Exposure Factors Handbook Table 15-77)]. While that exposure duration is representative of time spent engaged in “animal care” and may not represent the time volunteers were actively contacting the animal, HED believes the data are the most accurate representation of time spent with pets available. In addition, this exposure duration is a good match for the duration of time from the studies used to estimate the transfer coefficient for post-application exposure from contact with pets.

Item 2: Use of the biomonitoring data from the Davis, 2008 study

- As noted previously, OPP has determined that the biomonitoring data from the Davis, 2008 study cannot be used.

¹ HED notes that in the Hartz letter, the reference is to a 2007 article by Au Yeung, but the publication provided by Hartz is a 2006 publication.

- The OPP-internal science review for the Davis study² has concluded that the methods used for conduct of the collection of transferable TCVP residues from petting/rubbing of the dogs treated with TCVP pet collars are scientifically valid. In addition to the transferable residue data, the Davis study also includes 1) plasma cholinesterase (ChE) from treated dogs 2) T-shirt samples collected from children exposed to TCVP treated dogs and 3) urinary biomonitoring for adults and children exposure to TCVP treated dogs. For purposes of the TCVP risk assessment, EPA may rely only on the transferable residue data [in light of 40 CFR Part 26, subpart Q regarding ethical standards for assessing whether to rely on the results in human research in EPA actions] as these are the only data from the study that result in the potential for greater risks, are applicable to human exposures (in the case of the dog plasma ChE measures), or in the case of the urinary biomonitoring data, are useful given current scientific limitations (i.e., a physiologically based pharmacokinetic (PBPK) model applicable to TCVP).

Item 3: Mass Balance issue with HED's current assessment methodology for pet collars

- HED agrees with the Registrant that there is a mass balance issue with the current methodology. The approach taken has been selected as a conservative bounding exercise to address the uncertainty associated with the formulation of pet collars. HED believes the proposed steps/data development Hartz has identified will address these uncertainties and, as a result, will address the mass balance issue as well.

Item 4: Proposed data development

- HED agrees with and supports the proposed study to evaluate the release rate of TCVP pet collars. HED would be most interested in the initial kinetics of the collar during the first 30 days of use. If the Registrant chooses to conduct the full 210-day study, HED would request the data for the first 30 days be submitted once collected and analyzed so that it can be reviewed for potential use as a refinement of the TCVP pet collar assessment in advance of the remaining study days.
- HED also agrees and supports the proposed study to evaluate the weight percentage of TCVP and other components in the material being emitted from the collar following torsion/mechanical stress. This information would be critical to address the dust/liquid formulation uncertainty.
- A protocol for the proposed studies should be submitted to HED for review prior to its conduct.

² W. Britton. Science Review of "Davis et al., 2008. Assessing Intermittent Pesticide Exposure from Flea Control Collars Containing the Organophosphorus Insecticide Tetrachlorvinphos" for HSRB Consideration. D430707. 12/16/2015.

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 6/26/2017 8:57:10 PM
To: Doug Spilker [doug.spilker@bayer.com]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Robert Zolynas [robert.zolynas@bayer.com]
Subject: RE: TCVP: conference call request.

Thanks Doug, we are confirmed for 7/6 at 11 am for a half hr teleconference. Talk to you then!

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Monday, June 26, 2017 4:52 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Cc: Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Robert Zolynas <robert.zolynas@bayer.com>
Subject: RE: TCVP: conference call request.

Dear Khue,

The **Thursday 7/6 at 11 am Eastern** is perfect for us. Thanks for getting back to us so quickly.

Joining me on the call will be Dr. Robert Zolynas, the head of our Research & Regulatory Group.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751

Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com

Web: <http://www.bayer.com>

From: Nguyen, Khue [<mailto:Nguyen.Khue@epa.gov>]

Sent: Monday, June 26, 2017 3:46 PM

To: Doug Spilker

Cc: Anderson, Neil; Grable, Melissa; Robert Zolynas

Subject: RE: TCVP: conference call request.

Hi Doug,

Sure, we can arrange a quick teleconference. Unfortunately, our division director is not able to have this teleconference this week. My supervisor, Neil, is also out on vacation this week. Here are some proposed times when all of us will be available:

Thursday 7/6 at 11 am

Monday 7/10 at 1 pm

Tuesday 7/11 at 1:30 pm

Is a half hour enough time, or do you think this conversation will take longer than that?

The call in info for the teleconference:

Personal Matters / Ex. 6

Thanks,

Khue Nguyen

Chemical Review Manager

Risk Management and Implementation Branch 1

Pesticide Re-evaluation Division

Office of Pesticide Programs, EPA

703-347-0248

Nguyen.khue@epa.gov

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]

Sent: Monday, June 26, 2017 3:54 PM

To: Nguyen, Khue <Nguyen.Khue@epa.gov>; lhemsarth@hartz.com

Cc: Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Robert Zolynas <robert.zolynas@bayer.com>

Subject: RE: TCVP: conference call request.

Dear Ms. Nguyen,

Thank you for your follow-up email to our discussion on June 22, 2017 regarding the below subject. As I mentioned, Bayer will be submitting a letter to the Agency that addresses some very relevant issues related to TCVP and our uses. Before we submit the aforementioned letter, we would like to apprise you of its contents. Therefore, we request a brief conference call with you, your respective supervisor and Director Guilaran in the very near future, this week if possible.

Please let me know some times when you are available, and we will do our best to accommodate one of those dates and times.

Thank you for your assistance in this matter.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

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E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [<mailto:Nguyen.Khue@epa.gov>]
Sent: Thursday, June 22, 2017 3:43 PM
To: Doug Spilker; lhemsarth@hartz.com
Cc: Anderson, Neil; Grable, Melissa
Subject: TCVP: meeting request

Hi all,

We would like to meet with TCVP technical registrants and discuss the risks, the path forward for TCVP (in relation to the other organophosphate pesticides), and the pet uses for TCVP. Specifically, we want to discuss the pet collar use and how to move forward to address risks for pet collars.

Here are some proposed times when the team is available:

Thursday 7/6 from 2-3 pm; or from 3-4 pm
Wednesday 7/12 from 11 am-12 pm; or from 1-2 pm

Unfortunately, there are limited days when most of us are available—folks tend to be on vacation around July 4th. I am out of the office for 2 weeks in July as well. We appreciate your flexibility.

We encourage registrants to attend in person when they can, but we will open a teleconference line if you prefer to call in.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

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The information contained in this e-mail is for the exclusive use of the intended recipient(s) and may be confidential, proprietary, and/or legally privileged. Inadvertent disclosure of this message does not constitute a waiver of any privilege. If you receive this message in error, please do not directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.

Message

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To: Doug Spilker [doug.spilker@bayer.com]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Robert Zolynas [robert.zolynas@bayer.com]
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Personal Matters / Ex. 6

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
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Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

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Animal Health R&D, Regulatory Affairs
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Sent: Thursday, June 22, 2017 3:43 PM

To: Doug Spilker; lhemsarth@hartz.com

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Message

From: Joseph Conti [jconti@hartz.com]
Sent: 7/18/2017 7:42:22 PM
To: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; keller.kaitin@epa.gov
CC: Lance Hemsarh [lhemsarh@hartz.com]; Dr. Jeffrey Driver [Personal Matters / Ex. 6]; John Ross [jhross@surewest.net]; Yasushi Takeda [ytakeda@hartz.com]; Tatsuya Suto [tsuto@hartz.com]; Kei Tokumitsu [ktokumitsu@hartz.com]
Subject: Hartz Mountain TCVP Response
Attachments: tcvpepa 718 final.pdf

Per our meeting of July 11, 2017, we have provided a response along with time frames for the development of additional data for review by the Agency. We will continue to develop and work with outside laboratories to refine the estimates proposed and advise. We also will be sending protocols to the EPA for comment as they are developed.

Joe Conti
Sr. Director Regulatory & Quality
Hartz Mountain Corporation
201.271.4800 ext 7377

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The Hartz Mountain Corporation

Message

From: Anderson, Neil [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8996B61C04CE4E5CB9E35B323EE5E824-NEIL G. ANDERSON]
Sent: 7/25/2017 9:02:25 PM
To: Joseph Conti [jconti@hartz.com]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Keller, Kaitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a6b15adfd745c6ada1c121dec27ac4-Keller, Kai]; Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]
Subject: RE: TCVP Follow-up

Joe,

We shared your submission with the TCVP team and it is under review at the moment. We will get back to you as soon as we have questions or a response to share. Thank you for the submission and we will be in touch soon.

Regards,

Neil Anderson
Chief, Risk Management and Implementation Branch I
Pesticide Re-evaluation Division, Office of Pesticide Programs
US EPA (Mail Code 7508P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: 703-308-8187
anderson.neil@epa.gov

Visit us on the Web at: <http://www.epa.gov/pesticides/>

From: Joseph Conti [mailto:jconti@hartz.com]
Sent: Tuesday, July 25, 2017 1:22 PM
To: Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Keller, Kaitlin <keller.kaitlin@epa.gov>; Nguyen, Khue <Nguyen.Khue@epa.gov>
Subject: TCVP Follow-up

I wanted to follow-up on the Hartz Mountain TCVP proposal which we filed with the Agency last week. We are working with outside laboratories to find a lab and finalize a protocol. It is our intention to follow the prescribed timeline but it is very important that we receive concurrence from EPA on our plan forward and receive an update on rolling back the proposed NRDC response.

Joe Conti
Sr Director Regulatory & Quality
Hartz Mountain Corporation

This e-mail contains confidential and privileged information. If you think you received this e-mail in error, please advise sender by return e-mail, and then delete this e-mail message immediately.

The Hartz Mountain Corporation

Message

From: Doug Spilker [doug.spilker@bayer.com]
Sent: 7/27/2017 11:26:40 AM
To: Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]
CC: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]
Subject: Re: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Melissa, Thank you.

Douglas A. Spilker, Ph. D.
Bayer Animal Health

This message may be brief since it was sent from my iPhone (816-506-3102). Office #913-268-2751.

On Jul 26, 2017, at 5:14 PM, Grable, Melissa <Grable.Melissa@epa.gov> wrote:

<image002.gif>
Hi Doug,

Khue is back in the office tomorrow. We will checking into this and get back to you.

Thanks,
Melissa

Melissa Grable, Team Leader
U.S. Environmental Protection Agency
OCSPP/OPP/PRD/RMIB 1
grable.melissa@epa.gov
(703) 308-3953

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]
Sent: Wednesday, July 26, 2017 2:54 PM
To: Grable, Melissa <Grable.Melissa@epa.gov>
Subject: FW: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Hi Melissa,
I see that Khue is on vacation. Would you happen to know the status of the aforementioned letter being posted to the TCVP docket? I assume it would be posted in the comment section.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC

Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Doug Spilker
Sent: Wednesday, July 26, 2017 1:29 PM
To: Nguyen, Khue (Nguyen.Khue@epa.gov)
Subject: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Hi Khue,

I looked at the docket again today, and do not yet see our letter posted. If you know when it might be posted, we would appreciate an alert.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
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P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Doug Spilker
Sent: Thursday, July 06, 2017 1:58 PM
To: 'Nguyen, Khue'
Cc: Robert Zolynas; Anderson, Neil; Grable, Melissa; Biggio, Patricia
Subject: RE: TCVP Follow-up

Dear Ms. Nguyen,

Thank you again for setting up the discussion this morning. We as well thought it was a fruitful discussion.

As we discussed, Bayer requests you post the attached letter to the Tetrachlorvinphos (TCVP) Docket ID: EPA-HQ-OPP-2008-0316. At an appropriate time, Bayer Animal Health

would be very interested in sharing our knowledge regarding the use of TCVP-containing products on food animals and their surroundings. I have already discussed this with our technical staff, and we would suggest Bayer prepare a presentation and other information to apprise the Agency of how these products are used and their value, and would certainly welcome USDA's involvement. We should consider this later this year.

If there are any questions concerning this response, please contact me by telephone (913-268-2751) or e-mail (doug.spilker@bayer.com).

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [<mailto:Nguyen.Khue@epa.gov>]
Sent: Thursday, July 06, 2017 12:26 PM
To: Doug Spilker
Cc: Robert Zolynas; Anderson, Neil; Grable, Melissa; Biggio, Patricia
Subject: RE: TCVP Follow-up

Hi Doug,

Thanks for chatting with us. We thought it was a good conversation. Attached is the attendance sheet for the teleconference.

In case you can't read my chicken scratch handwriting, the attendees from EPA are:

Yu-Ting Guilaran
Charles "Billy" Smith
Neil Anderson
Melissa Grable
Patricia Biggio
And myself

As discussed, we look forward to receiving the memorandum addressing the 10X SF which is intended to be posted to the TCVP reg review docket and a separate request for voluntary cancellation of the pet collar products. EPA is interested in additional information on the livestock (poultry, cattle, swine) uses

of TCVP and we can get together to discuss those uses in the near future. We already sent some questions about these uses to USDA, so it might be possible to coordinate with USDA on this.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]
Sent: Thursday, July 06, 2017 12:55 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Cc: Robert Zolynas <robert.zolynas@bayer.com>
Subject: TCVP Follow-up

Hi Khue,
Thanks again for setting up the teleconference and getting the right people there. I thought it went well.

One of the action items from the call was for me to check to be sure that we did not have any other TCVP-containing pet products besides the two pet collars (EPA Reg. Nos. 11556-164 and -165).

I can confirm that the above listed are the only TCVP-containing pet products registered by Bayer.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
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Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

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ED_002155A_00003996-00004

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Appointment

From: Microsoft Outlook [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MICROSOFTEXCHANGE329E71EC88AE4615BBC36AB6CE41109EF7088051]
Sent: 7/25/2017 12:18:26 PM
To: Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]
Subject: Meeting Forward Notification: Follow-up meeting on TCVP - options presented by Hartz
Location: DCRoomPYS9671/Potomac-Yard-One
Start: 7/27/2017 8:00:00 PM
End: 7/27/2017 9:00:00 PM
Recurrence: (none)

Your meeting was forwarded

Lowe, Kelly has forwarded your meeting request to additional recipients.

Meeting

Follow-up meeting on TCVP - options presented by Hartz

Meeting Time

Thursday, July 27, 2017 4:00 PM-5:00 PM.

Recipients

Rickard, Kristin

Bacon, Laura

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Sent by Microsoft Exchange Server

Message

From: Doug Spilker [doug.spilker@bayer.com]
Sent: 6/26/2017 8:57:43 PM
To: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]
Subject: RE: TCVP: conference call request.

Thanks.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [mailto:Nguyen.Khue@epa.gov]
Sent: Monday, June 26, 2017 3:57 PM
To: Doug Spilker
Cc: Anderson, Neil; Grable, Melissa; Robert Zolynas
Subject: RE: TCVP: conference call request.

Thanks Doug, we are confirmed for 7/6 at 11 am for a half hr teleconference. Talk to you then!

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Monday, June 26, 2017 4:52 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Cc: Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Robert Zolynas <robert.zolynas@bayer.com>
Subject: RE: TCVP: conference call request.

Dear Khue,

The **Thursday 7/6 at 11 am Eastern** is perfect for us. Thanks for getting back to us so quickly.

Joining me on the call will be Dr. Robert Zolynas, the head of our Research & Regulatory Group.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

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E-mail: doug.spilker@bayer.com

Web: <http://www.bayer.com>

From: Nguyen, Khue [<mailto:Nguyen.Khue@epa.gov>]

Sent: Monday, June 26, 2017 3:46 PM

To: Doug Spilker

Cc: Anderson, Neil; Grable, Melissa; Robert Zolynas

Subject: RE: TCVP: conference call request.

Hi Doug,

Sure, we can arrange a quick teleconference. Unfortunately, our division director is not able to have this teleconference this week. My supervisor, Neil, is also out on vacation this week. Here are some proposed times when all of us will be available:

Thursday 7/6 at 11 am
Monday 7/10 at 1 pm
Tuesday 7/11 at 1:30 pm

Is a half hour enough time, or do you think this conversation will take longer than that?

The call in info for the teleconference:

Personal Matters / Ex. 6

Thanks,

Khue Nguyen
Chemical Review Manager

Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]
Sent: Monday, June 26, 2017 3:54 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>; lhemsarth@hartz.com
Cc: Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Robert Zolynas <robert.zolynas@bayer.com>
Subject: RE: TCVP: conference call request.

Dear Ms. Nguyen,
Thank you for your follow-up email to our discussion on June 22, 2017 regarding the below subject. As I mentioned, Bayer will be submitting a letter to the Agency that addresses some very relevant issues related to TCVP and our uses. Before we submit the aforementioned letter, we would like to apprise you of its contents. Therefore, we request a brief conference call with you, your respective supervisor and Director Guilaran in the very near future, this week if possible.

Please let me know some times when you are available, and we will do our best to accommodate one of those dates and times.

Thank you for your assistance in this matter.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA

Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [<mailto:Nguyen.Khue@epa.gov>]
Sent: Thursday, June 22, 2017 3:43 PM
To: Doug Spilker; lhemsarth@hartz.com
Cc: Anderson, Neil; Grable, Melissa
Subject: TCVP: meeting request

Hi all,

We would like to meet with TCVP technical registrants and discuss the risks, the path forward for TCVP (in relation to the other organophosphate pesticides), and the pet uses for TCVP. Specifically, we want to discuss the pet collar use and how to move forward to address risks for pet collars.

Here are some proposed times when the team is available:

Thursday 7/6 from 2-3 pm; or from 3-4 pm

Wednesday 7/12 from 11 am-12 pm; or from 1-2 pm

Unfortunately, there are limited days when most of us are available—folks tend to be on vacation around July 4th. I am out of the office for 2 weeks in July as well. We appreciate your flexibility.

We encourage registrants to attend in person when they can, but we will open a teleconference line if you prefer to call in.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

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Message

From: Doug Spilker [doug.spilker@bayer.com]
Sent: 6/26/2017 8:53:17 PM
To: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]
Subject: RE: TCVP: conference call request.

Sorry, I didn't answer your question regarding time. Yes, 30 minutes should be enough.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
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Tel: +1 913 268 2751
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E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [mailto:Nguyen.Khue@epa.gov]
Sent: Monday, June 26, 2017 3:46 PM
To: Doug Spilker
Cc: Anderson, Neil; Grable, Melissa; Robert Zolynas
Subject: RE: TCVP: conference call request.

Hi Doug,

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The call in info for the teleconference:

Personal Matters / Ex. 6

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]
Sent: Monday, June 26, 2017 3:54 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>; lhemsarth@hartz.com
Cc: Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Robert Zolynas <robert.zolynas@bayer.com>
Subject: RE: TCVP: conference call request.

Dear Ms. Nguyen,
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Please let me know some times when you are available, and we will do our best to accommodate one of those dates and times.

Thank you for your assistance in this matter.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

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Animal Health R&D, Regulatory Affairs
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Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [<mailto:Nguyen.Khue@epa.gov>]
Sent: Thursday, June 22, 2017 3:43 PM
To: Doug Spilker; lhemsarth@hartz.com
Cc: Anderson, Neil; Grable, Melissa
Subject: TCVP: meeting request

Hi all,

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Here are some proposed times when the team is available:

Thursday 7/6 from 2-3 pm; or from 3-4 pm

Wednesday 7/12 from 11 am-12 pm; or from 1-2 pm

Unfortunately, there are limited days when most of us are available—folks tend to be on vacation around July 4th. I am out of the office for 2 weeks in July as well. We appreciate your flexibility.

We encourage registrants to attend in person when they can, but we will open a teleconference line if you prefer to call in.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

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Message

From: Joseph Conti [jconti@hartz.com]
Sent: 7/11/2017 5:48:57 PM
To: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]; Dr. Jeffrey Driver [Personal Matters / Ex. 6] John Ross [jhross@surewest.net]
Subject: Agenda and Slides
Attachments: EPA Mtg 11Jul17_final.pptx

Flag: Follow up

Please find agenda for our discussion this afternoon. EPA had proposed the meeting, so we have left the opening statements and purpose for the Agency followed by our discussion. The attached slides will be used as a supplement to the Hartz discussion.

Agenda

1. Introductions
2. EPA meeting purpose and position
3. Discussion by Hartz
4. Steps Forward

We look forward to the opportunity and discussion,

Joe Conti
Sr. Director Regulatory & Quality
Hartz Mountain Corporation

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Message

From: Doug Spilker [doug.spilker@bayer.com]
Sent: 7/7/2017 3:20:26 PM
To: Gebken, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73ca222b226c48cf99caa899188a8c51-Richard J. Gebken]
CC: Rodia, Carmen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f7aa3e6a294482daf81528bd301e958-Carmen J Rodia]; Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]; Todd Frank [todd.frank@bayer.com]
Subject: RE: Revised Request for Voluntary Cancellations of EPA Reg. Nos. 11556-164 and 11556-165
Attachments: Gebken 07-07-17 TCVP collars Bayer AH cancel rev.pdf

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Gebken, Richard [mailto:Gebken.Richard@epa.gov]
Sent: Friday, July 07, 2017 9:40 AM
To: Doug Spilker
Cc: Rodia, Carmen; Nguyen, Khue; Todd Frank
Subject: RE: Request for Voluntary Cancellations of EPA Reg. Nos. 11556-164 and 11556-165

Thanks Doug,

You may want to consider revising the letter to waive the comment period, since we publish it in the FR.

Richard Gebken

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Friday, July 07, 2017 10:34 AM
To: Gebken, Richard <Gebken.Richard@epa.gov>
Cc: Rodia, Carmen <Rodia.Carmen@epa.gov>; McCall, Deborah <McCall.Deborah@epa.gov>; Nguyen, Khue

<Nguyen.Khue@epa.gov>; Todd Frank <todd.frank@bayer.com>

Subject: Request for Voluntary Cancellations of EPA Reg. Nos. 11556-164 and 11556-165

Dear Mr. Gebken,

Please find attached our letter requesting the voluntary cancellation of the TCVP-containing registrations of **Americare Rabon Flea & Tick Collar for Dogs (EPA Reg. No. 11556-164)** and **Americare Rabon Flea & Tick Collar for Cats (EPA Reg. No. 11556-165)**. We would appreciate prompt action on this request.

If you have any questions, please do not hesitate to call (913-268-2751).

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
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Bayer Animal Health
P.O. Box 390
Shawnee Mission, KS
66201-0390

Via email
July 7, 2017

Document Processing Desk (Non-PRIA Action)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken/PM 10

Subject: **Request for Voluntary Cancellations:**
Americare Rabon Flea & Tick Collar for Dogs (EPA Reg. No. 11556-164)
Americare Rabon Flea & Tick Collar for Cats (EPA Reg. No. 11556-165)

Dear Mr. Gebken:

Bayer HealthCare, Animal Health Division, requests the voluntary cancellation of the registrations of **Americare Rabon Flea & Tick Collar for Dogs (EPA Reg. No. 11556-164)** and **Americare Rabon Flea & Tick Collar for Cats (EPA Reg. No. 11556-165)**. We also waive the requirement of a comment period so that this action can be handled promptly.

No channels-in-trade materials exist for either product, as they were never commercialized by Bayer. We will appropriately indicate this on the next "Pesticide Registration Maintenance Fee List."

If you have any questions, please do not hesitate to call (913-268-2751).

Sincerely,

Douglas A. Spilker, Ph. D.
Manager, EPA Regulatory Affairs
Doug.Spilker@Bayer.com

Cc: K. Nguyen/PRD
D. McCall/RD

Message

From: Doug Spilker [doug.spilker@bayer.com]
Sent: 7/7/2017 2:34:06 PM
To: Gebken, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73ca222b226c48cf99caa899188a8c51-Richard J. Gebken]
CC: Rodia, Carmen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f7aa3e6a294482daf81528bd301e958-Carmen J Rodia]; McCall, Deborah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ccfb2eaa454c9da374de456b443162-Deborah L. McCall]; Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8b8-Nguyen, Khue]; Todd Frank [todd.frank@bayer.com]
Subject: Request for Voluntary Cancellations of EPA Reg. Nos. 11556-164 and 11556-165
Attachments: Gebken 07-07-17 TCVP collars Bayer AH cancel.pdf

Dear Mr. Gebken,

Please find attached our letter requesting the voluntary cancellation of the TCVP-containing registrations of **Americare Rabon Flea & Tick Collar for Dogs (EPA Reg. No. 11556-164)** and **Americare Rabon Flea & Tick Collar for Cats (EPA Reg. No. 11556-165)**. We would appreciate prompt action on this request.

If you have any questions, please do not hesitate to call (913-268-2751).

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
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E-mail: doug.spilker@bayer.com
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Bayer Animal Health
P.O. Box 390
Shawnee Mission, KS
66201-0390

Via email
July 7, 2017

Document Processing Desk (Non-PRIA Action)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken/PM 10

Subject: **Request for Voluntary Cancellations:**
Americare Rabon Flea & Tick Collar for Dogs (EPA Reg. No. 11556-164)
Americare Rabon Flea & Tick Collar for Cats (EPA Reg. No. 11556-165)

Dear Mr. Gebken:

Bayer HealthCare, Animal Health Division, requests the voluntary cancellation of the registrations of **Americare Rabon Flea & Tick Collar for Dogs (EPA Reg. No. 11556-164)** and **Americare Rabon Flea & Tick Collar for Cats (EPA Reg. No. 11556-165)**. No channels-in-trade materials exist for either product, as they were never commercialized by Bayer. We will appropriately indicate this on the next "Pesticide Registration Maintenance Fee List."

If you have any questions, please do not hesitate to call (913-268-2751).

Sincerely,

A handwritten signature in black ink, appearing to read "Doug A. Spilker".

Douglas A. Spilker, Ph. D.
Manager, EPA Regulatory Affairs
Doug.Spilker@Bayer.com

Cc: K. Nguyen/PRD
D. McCall/RD

Message

From: Doug Spilker [doug.spilker@bayer.com]
Sent: 7/6/2017 7:43:53 PM
To: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]
Subject: FW: TCVP Follow-up
Attachments: TCVP Docket Letter Bayer AH 07-06-2017.pdf

Here you go.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA

Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Doug Spilker
Sent: Thursday, July 06, 2017 1:58 PM
To: 'Nguyen, Khue'
Cc: Robert Zolynas; Anderson, Neil; Grable, Melissa; Biggio, Patricia
Subject: RE: TCVP Follow-up

Dear Ms. Nguyen,

Thank you again for setting up the discussion this morning. We as well thought it was a fruitful discussion.

As we discussed, Bayer requests you post the attached letter to the Tetrachlorvinphos (TCVP) Docket ID: EPA-HQ-OPP-2008-0316. At an appropriate time, Bayer Animal Health would be very interested in sharing our knowledge regarding the use of TCVP-containing products on food animals and their surroundings. I have already discussed this with our technical staff, and we would suggest Bayer prepare a presentation and other information to apprise the Agency of how these products are used and their value, and would certainly welcome USDA's involvement. We should consider this later this year.

If there are any questions concerning this response, please contact me by telephone (913-268-2751) or e-mail (doug.spilker@bayer.com).

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [<mailto:Nguyen.Khue@epa.gov>]
Sent: Thursday, July 06, 2017 12:26 PM
To: Doug Spilker
Cc: Robert Zolynas; Anderson, Neil; Grable, Melissa; Biggio, Patricia
Subject: RE: TCVP Follow-up

Hi Doug,

Thanks for chatting with us. We thought it was a good conversation. Attached is the attendance sheet for the teleconference.

In case you can't read my chicken scratch handwriting, the attendees from EPA are:

Yu-Ting Guilaran
Charles "Billy" Smith
Neil Anderson
Melissa Grable
Patricia Biggio
And myself

As discussed, we look forward to receiving the memorandum addressing the 10X SF which is intended to be posted to the TCVP reg review docket and a separate request for voluntary cancellation of the pet collar products. EPA is interested in additional information on the livestock (poultry, cattle, swine) uses of TCVP and we can get together to discuss those uses in the near future. We already sent some questions about these uses to USDA, so it might be possible to coordinate with USDA on this.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA

703-347-0248

Nguyen.khue@epa.gov

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]

Sent: Thursday, July 06, 2017 12:55 PM

To: Nguyen, Khue <Nguyen.Khue@epa.gov>

Cc: Robert Zolynas <robert.zolynas@bayer.com>

Subject: TCVP Follow-up

Hi Khue,

Thanks again for setting up the teleconference and getting the right people there. I thought it went well.

One of the action items from the call was for me to check to be sure that we did not have any other TCVP-containing pet products besides the two pet collars (EPA Reg. Nos. 11556-164 and -165).

I can confirm that the above listed are the only TCVP-containing pet products registered by Bayer.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

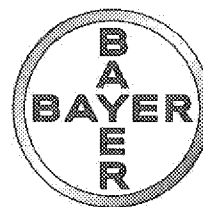
Bayer U.S. LLC
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E-mail: doug.spilker@bayer.com

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July 06, 2017

Bayer Animal Health
P.O. Box 390
Shawnee Mission, KS
66201-0390

Office of Pesticide Programs (7508P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Chemical Common Name: **Tetrachlorvinphos (TCVP)**; Chemical # 083702
Submission of additional information in response to the Agency's ***"Tetrachlorvinphos (TCVP) Human Health Draft Risk Assessment for Registration Review" and Reply to Request for Meeting***

Attn: Ms. Khue Nguyen, Chemical Review Manager
Risk Management and Implementation, Branch I
Pesticide Re-evaluation Division (7508P)

Dear Ms. Nguyen:

On 25 May 2017 the U.S. Environmental Protection Agency (EPA or Agency) published in the Federal Register a notice regarding the Registration Review of tetrachlorvinphos (TCVP).¹ The notice announced the availability of EPA's final occupational and residential exposure assessment for TCVP, and the explanation for the Agency's reliance on human research regarding the TCVP flea collar. In addition, the Agency placed in the docket other documents that the Agency considers relevant to the registration review of TCVP. While the Federal Registration Notice states a comment period is open for 35 days, closing July 24, 2017, the actual registration docket for TCVP shows that the exposure assessment is considered final, and the docket is not opened for comment.

On June 22, 2017 you sent to me an email requesting a meeting with the TCVP technical registrants, including Bayer Animal Health, to discuss the risks and a path forward for TCVP. Bayer believes that the TCVP docket as it now stands is misleading in regards to the status of the imposition of the FQPA 10x safety factor and that any discussion regarding potential risks of TCVP registered uses is premature until a final resolution by the Agency regarding the reliance on the cited epidemiology studies to create uncertainty regarding the FQPA safety factor.

¹ Registration Review; Draft Human Health and/or Ecological Risk Assessment(s), and Final Tetrachlorvinphos Occupational and Residential Exposure Risk Assessment, and the Agency's Decision to Rely on Data From Human Health Research; Notice of Availability. EPA-HQ_OPP-2015-0794; FRL-9957-98. 25 May 2015

Bayer believes that any discussion on risk mitigation for TCVP is premature. Bayer's position is consistent with the conclusion of the Health Effects Division, as addressed in the CropLife America section of the Revised Human Health Risk Assessment², which stated that "[a]ny interim or final registration review decision for TCVP could potentially be impacted by EPA consideration of the epidemiological studies identified in the CLA petition." Furthermore, it is inconsistent with the basis that the Agency stated regarding the denial of the PANNA and NRDC petition to revoke the tolerances of chlorpyrifos. The denial was based in part on the Agency's conclusion that the issues raised by the epidemiology studies raises novel issues that requires greater review and deliberation before any regulatory decisions can be reached.

As previously stated, Bayer believes that the docket as it currently stands creates an impression that the Agency has definitively concluded that the Agency is retaining the FQPA 10X safety factor based on epidemiology data. We believe this conclusion is not accurate and is not supported by the facts. Therefore, in addition to believing that a meeting is premature, Bayer requests that the record for TCVP be clarified and address the use, or non-use, of the available epidemiology studies mentioned below.

First, the Agency posted two memoranda in response to exposure related comments to preliminary organophosphate risk assessments.^{3,4} In the response to exposure-related comments the organophosphate document's section "Application of a 10x Database Uncertainty Factor for Workers" the Agency states that "[m]oreover, there is a large body of *in vivo* laboratory studies which show long-term behavioral effects from early life exposure, albeit at doses which cause acetylcholinesterase (AChE) inhibition. EPA considers the results of the toxicological studies relevant to the human population, as qualitatively supported by the results of epidemiology studies." This statement also is contained in the revised TCVP human health risk assessment.

This is a misstatement of fact for TCVP with regard to the *in vivo* studies and is contradicted by conclusions in the Agency's revised human health risk assessment. In its revised risk assessment the Agency concluded that "There is no evidence of quantitative or qualitative sensitivity in the developmental rat and rabbit studies or in the gestational (fetus) or juvenile components of the comparative cholinesterase assay (CCA) studies in rates. AChE data from the CCA studies suggest that the fetus is not more sensitive than the pregnant dam, and that pregnant females are not more sensitive than non-pregnant females with respect to cholinesterase inhibition. When comparing RBC BMD₁₀ (benchmark dose) estimates from across the acute (single dose) CCA and repeat dose CCA studies, it is apparent that there are no age-related differences. The acute and steady state PODs selected for oral exposure risk assessment are based on RBC AChE inhibition in the postnatal day 11 (PND11) and

² Tetrachlorvinphos: Revised Human Health Risk Assessment for Registration Review. DP Barcode:D436834, 21 December 2016.

³ Organophosphates: Response to Occupational and Residential Exposure-Related Comments on the Preliminary Organophosphate Human Health Risk Assessments, DP Barcode:D437200, 27 December 2016.

⁴ Tetrachlorvinphos: Revised Human Health Risk Assessment for Registration Review. DP Barcode:D436834, 21 December 2016.

postnatal day 21 (PND21) pups in the acute CCA since they provide the most robust dose-responses and are protective of all life states.”

Section 4.5.3 of the revised human health risk assessment also stated “The concern for susceptibility is low based on the lack of susceptibility following *in utero* exposure to TCVP in either the rat or rabbit developmental toxicity study or following *in utero* and/or pre-/post-natal exposure to TCVP in the 2-generation reproduction rat study.” “Furthermore, the effects observed in the DNT [study] occurred at a dose 70-fold higher than the point of departure (POD).” The EPA conclusion that TCVP has a complete animal toxicology database that does not demonstrate increased sensitivity to the fetus or juveniles contradicts the statement that a large body of animal study evidence demonstrates enhanced susceptibility.

Bayer believes that the docket should be corrected to clarify that the Agency has determined that the TCVP animal toxicology database is complete, that based on the data there is no evidence of enhanced susceptibility to the fetus or juvenile animals, and that the conclusion regarding an alleged large body of *in vivo* laboratory animal studies purporting to show long-term behavioral effects is contradicted by the TCVP animal toxicology database. Such a conclusion supports the reduction of the FQPA 10X safety factor to 1X.

Second, in the docket the Agency posted its response to comments regarding the September 2015 epidemiology literature review⁵ and based on its response to public comments the Agency also posted an updated literature review document.⁶ The posting of these two documents into the TCVP docket create the impression in the record that the Agency has made a final determination that the epidemiology literature review supports the retention of the FQPA 10X despite the robust animal toxicology database demonstrating no enhanced susceptibility. If this is the final determination, which we believe would not be correct, then a clear Agency position statement should state such, and if this is not the final determination, then that should also be clearly stated.

Bayer rejects the conclusions of the revised epidemiology literature review that OPP has relied upon to justify retaining the FQPA 10X safety factor, despite strong animal toxicology data to the contrary. The OPP position rests primarily on the results reported by the CCCEH researchers plus the results from the CHAMACOS and Mt. Sinai studies. Currently the researchers from these three organizations plus researchers from the University of Cincinnati HOME study have pooled their data and are publishing the results of the pooled data analysis. The analysis of child neurodevelopmental behavior at 24 months concluded that “Pooled summary estimates of prenatal exposure to OPs and neurodevelopment should be interpreted with caution because of significant heterogeneity in associations by center, race/ethnicity, and PON1 genotype.”⁷

⁵ Response to Comments for Public Comments Related to Applying the FQPA 10X Safety Factor for the Organophosphate Pesticides, DP Barcode:DP437042, 29 December 2016.

⁶ Updated Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphate Pesticides, DP Barcode:DP437043, 29 December 2016.

⁷ Engel, SM et. al., Prenatal Organophosphorus Pesticide Exposure and Child Neurodevelopment at 24 Months: An Analysis of Four Birth Cohorts, Environmental Health Perspectives, Vol. 124, No. 6, June 2016.

The Cincinnati HOME study has concluded that no associations existed between prenatal exposure to OPs and cognition at one to five years of age and that socioeconomic factors such as diet may play a role in the associations observed in the other epidemiology studies.⁸ This relationship between chemical exposures or stressors and non-chemical stressors such as socioeconomic factors is consistent with ongoing research by EPA's Office of Research and Development National Exposure Research Laboratory.

Bayer also believes that it is important to note that in April 2017, the Australian Pesticides and Veterinary Medicine Authority (APVMA) published a hazard review of chlorpyrifos that included an evaluation of the EPA reliance on the epidemiology data.⁹ The APVMA stated the following regarding reliance on the epidemiology studies that EPA has relied upon to justify increasing the FQPA safety factor to 10X:

However, due to justified concerns regarding the reported outcomes for infants of the CCCEH cohort, it was considered prudent to ensure that the chlorpyrifos toxicology assessment considered all available literature on the subject, including a detailed appraisal of the most contemporary clinical neurodevelopmental toxicity studies of animals. For this reason, the APVMA has undertaken a comprehensive assessment of additional neurodevelopmental studies of animals as part of this supplementary report to investigate reported sensitivity of women of child bearing age and infants, and examine the potential for effects to be occurring at doses below those which have long been associated with the most sensitive effects on cholinesterase inhibition in humans. After reviewing the most contemporary literature on the neurodevelopmental toxicity of chlorpyrifos in animals, including studies investigating potential modes of action through cholinergic or non-cholinergic pathways, there appears to be insufficient evidence to support a definitive mode of action other than AChE inhibition in adults, dams, or offspring exposed to chlorpyrifos. On this basis, the APVMA considers that the use of AChE inhibition as the key endpoint for the chlorpyrifos regulatory risk assessment remains appropriate. For this reason, the current health based guidance values (ADI and ARfD) for chlorpyrifos remain appropriate and continue to be protective of all population subgroups, including women of child bearing age and infants.

Finally, the European Food Safety Authority (EFSA) has published a draft opinion regarding improving the reliability and quality of epidemiology studies for potential use in pesticide risk assessment.¹⁰ The draft opinion is based on the 2013 EFSA finding that the quality of the epidemiology evidence is usually low and that many biases likely affect the results to the extent that firm conclusions cannot be drawn. Currently it is the position of EFSA that the use of epidemiology studies in the regulatory arena is a matter of concern which does not currently allow their use under EU Regulation No. 1107/2009.

In conclusion, the animal toxicology database demonstrates that there is no evidence of enhanced susceptibility of the fetus and juvenile resulting from exposure to TCVP and that consistent with the conclusions of APVMA and EFSA, there exists significant concerns regarding reliance on the epidemiological data in the regulatory risk assessment. The position of these two regulatory agencies

⁸ Donauer, S. et.al., An Observational Study to Evaluate Associations Between Low-Level Gestational Exposure to Organophosphate Pesticides and Cognition During Early Childhood. *Am J Epidemiol.* 2016;184(5):410-418.

⁹ Reconsideration of chlorpyrifos: supplementary toxicology assessment report, Australian Pesticides and Veterinary Medicines Authority 2017

¹⁰ Scientific Opinion of the PPR Panel on the follow-up of the findings of the External Scientific Report "Literature review of epidemiological studies linking exposure to pesticides and health effects", EFSA-Q-2014-00481.

supports the position of Bayer that the uncertainty regarding the epidemiology data does not affect the Agency's previous determination that a reasonable certainty of no harm exists for TCVP based on a 100X uncertainty factor.

Thank you for your attention to this matter. Bayer requests you post this letter to TCVP Docket ID: EPA-HQ-OPP-2008-0316, clarify the EPA's position on use of the epidemiology data, and use a safety factor of 1X that is supported by the TCVP animal toxicology database for a 100X uncertainty factor. We respectively decline to meet with the Agency to discuss risk mitigation until the Agency makes a final determination of the FQPA safety factor for TCVP.

If there are any questions concerning this response, please contact me by telephone (913-268-2751) or e-mail (doug.spilker@bayer.com).

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas A. Spilker", followed by a long horizontal line.

Douglas A. Spilker, Ph. D.
Manager, EPA Regulatory Affairs

cc: Yu-Ting Guilaran, Director, PRD
Neil Anderson, Branch Chief, RMIB I - PRD

Message

From: Joseph Conti [jconti@hartz.com]
Sent: 8/7/2017 3:27:17 PM
To: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]
CC: Dr. Jeffrey Driver [Personal Matters / Ex. 6]; John Ross [jhross@surewest.net]; Lance Hemsarth [lhemsarth@hartz.com]; Keith Goldman [kgoldman@hartz.com]; Yasushi Takeda [ytakeda@hartz.com]
Subject: Proposal/Time Lines
Attachments: tcvp schedule (3)87_JRed (1) (1).docx; TCVP Collar Testing AI loss87a (2) (4) (1) (1).xlsx

Attached is a proposal and timeline for discussion today. We understand that EPA has requested the meeting to comment on our July 18 submission and the attached testing and timelines may be altered based on our call.

Joe

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The Hartz Mountain Corporation

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 7/28/2017 5:22:09 PM
To: Doug Spilker [doug.spilker@bayer.com]
Subject: RE: TCVF Docket ID: EPA-HQ-OPP-2008-0316

Thanks Doug. We had a great trip filled with hiking, whitewater rafting, and cabin camping. Kayaking up to a glacier sounds amazing. We hiked on a glacier at one point. Alaska is really gorgeous.

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Friday, July 28, 2017 10:43 AM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Subject: RE: TCVF Docket ID: EPA-HQ-OPP-2008-0316

Hi Khue,
Thanks for your response. I was able to find it.

I hope your hiking went well in Alaska. We took the easy way and had a family outing on an Alaskan cruise of inland passage in May. We had a young child with us so we didn't do the land portion. Maybe next time. My wife, daughter and daughter-in-law did take a hike and then kayaked up to one of the glaciers. The "boys" took a train ride up into the mountains and the Yukon Territory that day. Beautiful country.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
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E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [mailto:Nguyen.Khue@epa.gov]
Sent: Thursday, July 27, 2017 5:19 PM
To: Doug Spilker
Cc: Anderson, Neil; Grable, Melissa
Subject: RE: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Hi Doug,

I just checked regulations.gov and the document has been posted (see image below). Usually it takes the docket staff about 2 weeks to process this sort of request.

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Tetrachlorvinphos (Gardona): Registration Review Docket Opening

Docket Browser Return to Docket Folder Summary

Docket ID: EPA-HQ-OPP-2008-0316 Agency: Environmental Protection Agency (EPA)

Summary:
For further information contact: James Parker (703) 306-0469 Mail code (7508P)

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Document SubType

Comment Submitted by Douglas Spilker Ph.D., Manager, EPA Regulatory Affairs, Bayer Animal Health
See Attached
Public Submission | Posted: 07/27/2017 | ID: EPA-HQ-OPP-2008-0316-0075
Comment Period Closed

Comment submitted by Douglas A. Spilker, Ph.D., Bayer HealthCare
See attached file(s)
Public Submission | Posted: 12/14/2016 | ID: EPA-HQ-OPP-2008-0316-0051
Comment Period Closed
May 11, 2016 11:59 PM ET

Comment submitted by Natural Resources Defense Council (NRDC)
Attached please find comments from The Natural Resources Defense Council (NRDC). We appreciate EPA's review and consideration of the peer-reviewed scientific literature as part...
Public Submission | Posted: 05/12/2016 | ID: EPA-HQ-OPP-2008-0316-0049
Comment Period Closed
May 11, 2016 11:59 PM ET

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Thursday, July 27, 2017 7:27 AM
To: Grable, Melissa <Grable.Melissa@epa.gov>

Cc: Nguyen, Khue <Nguyen.Khue@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>

Subject: Re: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Melissa, Thank you.

Douglas A. Spilker, Ph. D.

Bayer Animal Health

This message may be brief since it was sent from my iPhone (816-506-3102). Office #913-268-2751.

On Jul 26, 2017, at 5:14 PM, Grable, Melissa <Grable.Melissa@epa.gov> wrote:

<image002.gif>

Hi Doug,

Khue is back in the office tomorrow. We will checking into this and get back to you.

Thanks,

Melissa

Melissa Grable, Team Leader
U.S. Environmental Protection Agency
OCSPP/OPP/PRD/RMIB 1
grable.melissa@epa.gov
(703) 308-3953

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]

Sent: Wednesday, July 26, 2017 2:54 PM

To: Grable, Melissa <Grable.Melissa@epa.gov>

Subject: FW: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Hi Melissa,

I see that Khue is on vacation. Would you happen to know the status of the aforementioned letter being posted to the TCVP docket? I assume it would be posted in the comment section.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA

Tel: +1 913 268 2751

Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com

Web: <http://www.bayer.com>

From: Doug Spilker
Sent: Wednesday, July 26, 2017 1:29 PM
To: Nguyen, Khue (Nguyen.Khue@epa.gov)
Subject: TCVP Docket ID: EPA-HQ-OPP-2008-0316

Hi Khue,

I looked at the docket again today, and do not yet see our letter posted. If you know when it might be posted, we would appreciate an alert.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Doug Spilker
Sent: Thursday, July 06, 2017 1:58 PM
To: 'Nguyen, Khue'
Cc: Robert Zolynas; Anderson, Neil; Grable, Melissa; Biggio, Patricia
Subject: RE: TCVP Follow-up

Dear Ms. Nguyen,

Thank you again for setting up the discussion this morning. We as well thought it was a fruitful discussion.

As we discussed, Bayer requests you post the attached letter to the Tetrachlorvinphos (TCVP) Docket ID: EPA-HQ-OPP-2008-0316. At an appropriate time, Bayer Animal Health would be very interested in sharing our knowledge regarding the use of TCVP-containing products on food animals and their surroundings. I have already discussed this with our technical staff, and we would suggest Bayer prepare a presentation and other information to apprise the Agency of how these products are used and their value, and would certainly welcome USDA's involvement. We should consider this later this year.

If there are any questions concerning this response, please contact me by telephone (913-268-2751) or e-mail (doug.spilker@bayer.com).

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
USA
Tel: +1 913 268 2751
Mobile: +1 816 506 3102

E-mail: doug.spilker@bayer.com
Web: <http://www.bayer.com>

From: Nguyen, Khue [<mailto:Nguyen.Khue@epa.gov>]
Sent: Thursday, July 06, 2017 12:26 PM
To: Doug Spilker
Cc: Robert Zolynas; Anderson, Neil; Grable, Melissa; Biggio, Patricia
Subject: RE: TCVP Follow-up

Hi Doug,

Thanks for chatting with us. We thought it was a good conversation. Attached is the attendance sheet for the teleconference.

In case you can't read my chicken scratch handwriting, the attendees from EPA are:

Yu-Ting Guilaran
Charles "Billy" Smith
Neil Anderson
Melissa Grable
Patricia Biggio
And myself

As discussed, we look forward to receiving the memorandum addressing the 10X SF which is intended to be posted to the TCVP reg review docket and a separate request for voluntary cancellation of the pet collar products. EPA is interested in additional information on the livestock (poultry, cattle, swine) uses of TCVP and we can get together to discuss those uses in the near future. We already sent some questions about these uses to USDA, so it might be possible to coordinate with USDA on this.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA

703-347-0248

Nguyen.khue@epa.gov

From: Doug Spilker [<mailto:doug.spilker@bayer.com>]

Sent: Thursday, July 06, 2017 12:55 PM

To: Nguyen, Khue <Nguyen.Khue@epa.gov>

Cc: Robert Zolynas <robert.zolynas@bayer.com>

Subject: TCVP Follow-up

Hi Khue,

Thanks again for setting up the teleconference and getting the right people there. I thought it went well.

One of the action items from the call was for me to check to be sure that we did not have any other TCVP-containing pet products besides the two pet collars (EPA Reg. Nos. 11556-164 and -165).

I can confirm that the above listed are the only TCVP-containing pet products registered by Bayer.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC
Animal Health R&D, Regulatory Affairs
P.O. Box 390
Shawnee, KS 66201
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The information contained in this e-mail is for the exclusive use of the intended recipient(s) and may be confidential, proprietary, and/or legally privileged. Inadvertent disclosure of this message does not constitute a waiver of any privilege. If you receive this message in error, please do not directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.

The information contained in this e-mail is for the exclusive use of the intended recipient(s) and may be confidential, proprietary, and/or legally privileged. Inadvertent disclosure of this message does not constitute a waiver of any privilege. If you receive this message in error, please do not directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 7/11/2017 9:11:45 PM
To: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Britton, Wade [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c4124ab767b4c96b4b436bd02bccfbb-Wade T Britton]; Lowe, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ed25a8b48b1425a803ec6bbbe1e2590-Kelly M Lowe]; Metzger, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=655bc1c05459419d8bb3ba9a16568c3f-Michael S. Metzger]; Drew, Danette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a99dc94fd974fb6a26f9e35829f881c-Danette Drew]; Taylor, Linda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbfa6aa22daf4af8ba2e13991525a046-Linda Taylor]; Smith, Charles [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74d894a08f0b4d079b1632049bc5ebf4-Charles William Smith]; Atwood, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=552e92e6709540b0830411be42bd6405-Donald Atwood]; Smearman, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24add0e60ce64b7db49f0428340fc9d7-Stephen Smearman]; Myers, Clayton (Myers.Clayton@epa.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35804056c778423d8efb93c5d16a6a01-Myers, Clayton]
CC: Biggio, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a9a640a9a2941c5a9be1c4967e71718-Biggio, Pat]; Cook, Colwell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=22d418fa2a104eb8ba569013d708782f-Colwell A Cook]
Subject: tcvp: teleconference notes
Attachments: TCVP notes from 7.11.17 teleconference.docx; sign in sheet 7.11.17 telecon with hartz.pdf

I drafted notes from today's teleconference with Hartz. Please look at the attached and let me know if I mischaracterized anything. I will send notes to Hartz tomorrow, so **send me comments by 3pm Wednesday**.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

7/10/17: TCVP—teleconference with Hartz

Name	Organization	Email
Khue Nguyen	PRD/OPP	Nguyen.khue@epa.gov
Joe Lando	Hart 2	ilando.j@hart2.com via phone
Jeffrey Davis	Hart 2	via phone
John D. Puss	Hart 2	via phone
Melissa Grobie	EPA/PRD	grobie.melissa@epa.gov
Steve Smeacum	EPA/BEAD/ETB	smeacum.steph@epa.gov
Don Atwood	EPA/BEAD/BA B	atwood.donald@epa.gov
Clayton Myers	EPA/BEAD/BA B	myers.clayton@epa.gov
Alfred Brithan	EPA/HED	brithan.alfred@epa.gov
Bill Smith	EPA/PRD	smith.charles@epa.gov
Colwell Cook	EPA/BEAD/	cook.colwell@epa.gov
Patricia Biggio	EPA/PRD	biggio.patricia@epa.gov
Neil Anderson	PRD	Anderson.Neil@epa.gov
Michael Metzger	HKS	metzger.michael@epa.gov
Linda Yang	HEIS (on phone)	

Message

From: Joseph Conti [jconti@hartz.com]
Sent: 7/14/2017 1:11:45 PM
To: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc8-Nguyen, Khue]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Dr. Jeffrey Driver [Personal Matters / Ex. 6] John Ross [jhross@surewest.net]
CC: Yasushi Takeda [ytakeda@hartz.com]; Lance Hemsarh [lhemsarh@hartz.com]; Kei Tokumitsu [ktokumitsu@hartz.com]; Tatsuya Suto [tsuto@hartz.com]; William Fornshell [wfornshell@hartz.com]; Anna McGrath [amcgrath@hartz.com]
Subject: EPA Recorded TCVP Meeting Minutes with Hartz Comments
Attachments: TCVP.epa minutes 71117.docx; EPA Mtg 11Jul17_final (1).pptx

Attached are our revisions to the EPA minutes for the TCVP teleconference of July 11, 2017.

Joe Conti
Sr. Director Regulatory & Quality
Hartz Mountain Corporation

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The Hartz Mountain Corporation

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 7/12/2017 8:37:39 PM
To: Joseph Conti [jconti@hartz.com]; Dr. Jeffrey Driver [Personal Matters / Ex. 6] John Ross [jhross@surewest.net]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]
Subject: TCVP teleconference notes
Attachments: TCVP notes from 7.11.17 teleconference_post hed edits.docx

Hi,

Here are draft notes for the TCVP teleconference. Please review and let us know if we have mischaracterized anything.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Nguyen, Khue
Sent: Tuesday, July 11, 2017 5:55 PM
To: 'Joseph Conti' <jconti@hartz.com>; Dr. Jeffrey Driver [Personal Matters / Ex. 6] John Ross <jhross@surewest.net>
Cc: Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>
Subject: RE: Agenda and Slides

Hi all,

Thanks for being on the phone with us this afternoon. Attached is the sign-in sheet for the teleconference. While I am away on vacation during the next two weeks, please make sure to copy the following folks on all correspondence, including the submission of any open lit data:

Melissa Grable: grable.melissa@epa.gov (703-308-3953)
Neil Anderson: Anderson.neil@epa.gov (703-308-8187)

I'm working on gathering notes from the teleconference, and will send them tomorrow.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]

Sent: Tuesday, July 11, 2017 1:49 PM

To: Nguyen, Khue <Nguyen.Khue@epa.gov>; Dr. Jeffrey Driver <Personal Matters / Ex. 6>; John Ross <jhross@surewest.net>

Subject: Agenda and Slides

Please find agenda for our discussion this afternoon. EPA had proposed the meeting, so we have left the opening statements and purpose for the Agency followed by our discussion. The attached slides will be used as a supplement to the Hartz discussion.

Agenda

1. Introductions
2. EPA meeting purpose and position
3. Discussion by Hartz
4. Steps Forward

We look forward to the opportunity and discussion,

Joe Conti
Sr. Director Regulatory & Quality
Hartz Mountain Corporation

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The Hartz Mountain Corporation

TCVP: notes and action items for 7/11/17 teleconference with Hartz

EPA indicated that it intended to publish the proposed interim registration review decision for TCVP in September 2017. The focus of the proposed decision is the pet uses. EPA is awaiting a final decision on the use of the 10X FQPA database uncertainty factor for all the organophosphates, and so the agency intends to address dietary, occupational, and eco risks at a later date.

Hartz thought implementing risk mitigation for pet uses was premature and thought there was room for refinement in EPA's current risk assessment. Hartz put forward several proposals for refinement via PowerPoint slides, including the use of adult biomonitoring data for children, use of information on timed contact with pets and frequency of contact with pets, and refining the mass balance estimates which is currently too conservative. EPA pointed Hartz to its most recent "response to comments" document for the occupational and residential assessment, where most of these comments were already addressed. EPA did not have a chance to examine the NERL data cited in Hartz' slides relating to contact with treated pets (i.e., number and duration of pet contacts), but indicated that Hartz should submit these studies as soon as possible, including any raw data.

EPA indicated that it was interested in data which might help refine the number and duration of pet contact inputs. EPA discussed recent registrant data for pet collars that sought to determine what fraction of the collar was liquid and what fraction was solid. Having access to similar data for TCVP could potentially impact the risk picture. Hartz was open to working with EPA on developing additional data, but was concerned about the September deadline.

EPA's timeline is spurred by its obligation to respond to NRDC's petition for the pet uses. EPA indicated that Hartz should submit a solid proposal describing what data will be developed and a timeline for the submission of this data in the next few weeks. EPA does not have flexibility to extend the September deadline without more concrete information. Hartz said it needed to discuss internally. Hartz agreed to submit a letter of intent with a proposed timeline for the key elements discussed by Tuesday 7/18.

Action items from teleconference:

- 1) Hartz will submit a letter of intent with a proposed schedule for submission of key elements discussed (including raw data for the NERL studies, a data development proposal, and a schedule for data development) by Tuesday 7/18/17
- 2) Hartz will submit to EPA the NERL data cited in its slides (with raw data) for EPA's review (NERL studies received post-meeting, awaiting raw data)
- 3) Hartz will submit a data development proposal and a schedule for data development (date not yet determined)
- 4) EPA will send contact information for Neil and Melissa, who are the alternate contacts while Khue is on vacation (completed post-meeting)

Message

From: Britton, Wade [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6C4124AB767B4C96B4B436BD02BCCFBB-WADE T BRITTON]
Sent: 7/12/2017 11:59:05 AM
To: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfc88-Nguyen, Khue]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Lowe, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ed25a8b48b1425a803ec6bbbe1e2590-Kelly M Lowe]; Metzger, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=655bc1c05459419d8bb3ba9a16568c3f-Michael S. Metzger]; Drew, Danette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a99dc94fd974fb6a26f9e35829f881c-Danette Drew]; Taylor, Linda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbfa6aa22daf4af8ba2e13991525a046-Linda Taylor]; Smith, Charles [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74d894a08f0b4d079b1632049bc5ebf4-Charles William Smith]; Atwood, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=552e92e6709540b0830411be42bd6405-Donald Atwood]; Smearman, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24add0e60ce64b7db49f0428340fc9d7-Stephen Smearman]; Myers, Clayton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35804056c778423d8efb93c5d16a6a01-Myers, Clayton]
CC: Biggio, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a9a640a9a2941c5a9be1c4967e71718-Biggio, Pat]; Cook, Colwell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=22d418fa2a104eb8ba569013d708782f-Colwell A Cook]
Subject: RE: tcvp: teleconference notes
Attachments: TCVP notes from 7.11.17 teleconference_WB.docx

Hi Khue - Please see my edits in the attached. Wade



Wade Britton, MPH
Environmental Health Scientist
Risk Assessment Branch IV
Health Effects Division
Office of Pesticide Programs, US EPA
(703) 308-0139

From: Nguyen, Khue
Sent: Tuesday, July 11, 2017 5:12 PM
To: Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Britton, Wade <Britton.Wade@epa.gov>; Lowe, Kelly <Lowe.Kelly@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Drew, Danette <Drew.Danette@epa.gov>; Taylor, Linda <Taylor.Linda@epa.gov>; Smith, Charles <Smith.Charles@epa.gov>; Atwood, Donald <Atwood.Donald@epa.gov>; Smearman, Stephen <Smearman.Stephen@epa.gov>; Myers, Clayton <Myers.Clayton@epa.gov>
Cc: Biggio, Patricia <biggio.patricia@epa.gov>; Cook, Colwell <cook.colwell@epa.gov>
Subject: tcvp: teleconference notes

I drafted notes from today's teleconference with Hartz. Please look at the attached and let me know if I mischaracterized anything. I will send notes to Hartz tomorrow, so **send me comments by 3pm Wednesday**.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 7/27/2017 9:54:30 PM
To: Joseph Conti [jconti@hartz.com]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Dr. Jeffrey Driver [Personal Matters / Ex. 6]; John Ross [jhross@surewest.net]
Subject: RE: EPA Recorded TCVP Meeting Minutes with Hartz Comments
Attachments: TCVP.epa meeting minutes with hartz edits 7.27.17.docx

Hi Joe,

Here are the final meeting minutes, with edits from Hartz incorporated, for your records. The only suggested change we did not make was the reference to the Hartz slides as appendix 1—we don't think that is necessary. We will be posting a shorter meeting summary for the public docket, as is PRD's custom with all external meetings.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]
Sent: Friday, July 14, 2017 9:12 AM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Dr. Jeffrey Driver [Personal Matters / Ex. 6]; John Ross <jhross@surewest.net>
Cc: Yasushi Takeda <yakeda@hartz.com>; Lance Hemsarh <lhemsarh@hartz.com>; Kei Tokumitsu <ktokumitsu@hartz.com>; Tatsuya Suto <tsuto@hartz.com>; William Fornshell <wfornshell@hartz.com>; Anna McGrath <amcgrath@hartz.com>
Subject: EPA Recorded TCVP Meeting Minutes with Hartz Comments

Attached are our revisions to the EPA minutes for the TCVP teleconference of July 11, 2017.

Joe Conti
Sr. Director Regulatory & Quality
Hartz Mountain Corporation

This e-mail contains confidential and privileged information. If you think you received this e-mail in error, please advise sender by return e-mail, and then delete this e-mail message immediately.

The Hartz Mountain Corporation

TCVP: EPA notes and action items for 7/11/17 teleconference with Hartz including Hartz revisions

EPA indicated that it intended to publish the proposed interim registration review decision for TCVP in September 2017. The focus of the proposed decision is the pet uses. EPA is awaiting a final decision on the use of the 10X FQPA database uncertainty factor for all the organophosphates, and so the agency intends to address dietary, occupational, and eco risks at a later date.

Hartz thought implementing risk mitigation for pet uses was premature and believes there was room for refinement in EPA's current risk assessment. Hartz put forward several proposals for refinement via PowerPoint slides, including the use of adult biomonitoring data for children, use of information on timed contact with pets and frequency of contact with pets, and refinements based on mass balance considerations. EPA pointed Hartz to its most recent "response to comments" document for the occupational and residential assessment, where most of these comments were already addressed. Hartz indicated that in their view, the proposed refinements have not been adequately addressed by EPA's "response to comments" and requested further consideration, *e.g.*, utilization of open literature publications, and associated data regarding pet contact duration and frequency, mass balance consideration, and use of adult biomonitoring data, that included participants providing glove dosimetry data currently being used by EPA. EPA did not have a chance to examine the NERL data cited in Hartz' slides relating to contact with treated pets (*i.e.*, number and duration of pet contacts), but indicated that Hartz should submit these studies as soon as possible, including any raw data for review.

EPA indicated that it was interested in data which might help refine the number and duration of pet contact inputs. EPA discussed recent registrant data for pet collars that sought to determine what fraction of the collar was liquid and what fraction was solid. Having access to similar data for TCVP could potentially impact the risk picture. Hartz was open to working with EPA on developing additional data, but was concerned about the September deadline.

EPA's timeline is spurred by its obligation to respond to NRDC's petition for the pet uses. EPA indicated that Hartz should submit a solid proposal describing what data will be developed and a timeline for the submission of this data in the next few weeks. EPA does not have flexibility to extend the September deadline without more concrete information. Hartz said it needed to discuss internally. Hartz agreed to submit a letter of intent with a proposed timeline for the key elements discussed by Tuesday 7/18.

Action items from teleconference:

1. Hartz agreed to submit a letter of intent with a proposed schedule for submission of key elements discussed (including raw data for the NERL studies if available, a data development proposal, and a schedule for data development) by Tuesday 7/18/17
2. Hartz will submit to EPA the NERL data cited in its slides (with raw data) for EPA's review (NERL studies received post-meeting, awaiting raw data)
3. Hartz will submit a data development proposal and a schedule for data development (date not yet determined)
4. EPA will send contact information for Neil and Melissa, who are the alternate contacts while Khue is on vacation (completed post-meeting)

Message

From: Anderson, Neil [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8996B61C04CE4E5CB9E35B323EE5E824-NEIL G. ANDERSON]
Sent: 8/30/2017 5:14:09 PM
To: Keller, Kaitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a6b15adfd745c6ada1c121dec27ac4-Keller, Kai]
Subject: FW: Monthly Program Review Slides
Attachments: FY17 Q4 PID Monthly Chemical Review Meeting Slides_08_29_17.version for DDs.pptx

From: Grable, Melissa
Sent: Tuesday, August 29, 2017 5:06 PM
To: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; Nesci, Kimberly <Nesci.Kimberly@epa.gov>; Anderson, Brian <Anderson.Brian@epa.gov>; Pease, Anita <Pease.Anita@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Cc: McNally, Robert <Mcnally.Robert@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Knizner, Steve <Knizner.Steve@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Kenny, Daniel <Kenny.Dan@epa.gov>; OPP PRD Managers <OPP_PRD_Managers@epa.gov>
Subject: Monthly Program Review Slides

Attached are the monthly program review slides for this Thursday, August 31st. Yu-Ting asked me to send these along and ask for review comments by COB tomorrow, Wednesday, August 30th.

Thanks,
Melissa

Melissa Grable, Team Leader
U.S. Environmental Protection Agency
OCSPP/OPP/PRD/RMIB 1
grable.melissa@epa.gov
(703) 308-3953

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 8/31/2017 2:34:47 PM
To: Joseph Conti [jconti@hartz.com]
CC: Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]
Subject: TCVP teleconference sign-in sheet
Attachments: tcvp.signin sheet hartz telecom 8.24.17.pdf

Hi Joe,

Here is the sign-in sheet from last week's teleconference for TCVP, for your records.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Nguyen, Khue
Sent: Wednesday, August 30, 2017 6:54 PM
To: 'Joseph Conti' <jconti@hartz.com>
Cc: Grable, Melissa <Grable.Melissa@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>
Subject: TCVP follow up

Hi Joe,

I am back from vacation. Attached please find the notes from the TCVP teleconference last week (Melissa put these together). Please review and let us know if we mischaracterized anything.

We want to set up a follow up discussion to talk about all the protocols (including the expected analytical protocol) and discuss timing for study initiation. Here are some proposed times during the week of September 11th:

Mon 9/11, 11 am-12 pm; or 1-2 pm
Wed 9/13, 10-11 am
Thurs 9/14, 2-3 pm

Folks likely in attendance from our end will be: Neil Anderson (PRD), Melissa Grable (PRD), Trish Biggio (PRD), Wade Britton (HED), Kelly Lowe (HED), Kristin Rickard (HED), Laura Bacon (HED), Danette Drew (HED), Mike Metzger (HED), and myself

Let me know when works best.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [<mailto:jconti@hartz.com>]

Sent: Thursday, August 24, 2017 11:30 AM

To: Nguyen, Khue <Nguyen.Khue@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>

Cc: Dr. Jeffrey Driver [**Personal Matters / Ex. 6**] John Ross <jhross@surewest.net>; Lance Hemsarth <lhemsarth@hartz.com>; Keith Goldman <kgoldman@hartz.com>; Anna McGrath <amcgrath@hartz.com>

Subject: Hartz Mountain - TCVP

I have attached a test outline for the on animal collar testing. This is an outline and we are continuing to work with Clinvet to finalize a protocol, which will then be submitted for your review. Please advise and forward agenda for meeting today.

Joe Conti

Please confirm call-in number will be **Personal Matters / Ex. 6**

This e-mail contains confidential and privileged information. If you think you received this e-mail in error, please advise sender by return e-mail, and then delete this e-mail message immediately.

The Hartz Mountain Corporation

EPA Meeting Attendance Sheet

Meeting: HARTZ discussion for TCUP protocols

Date: 8/24/17 Time: 3-4 Room: 9671

Name	Division/Branch
------	-----------------

Patricia Biggio	PRD
-----------------	-----

Kristin Rickard	HED
-----------------	-----

Kelly Looze	HED
-------------	-----

Wade Britton	HED
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Jeff Dawson	HED
-------------	-----

Melissa Grable	PRD
----------------	-----

Laura Bacon	HED
-------------	-----

On Phone: from Hartz

Jeff Driver	Risk Sciences
-------------	---------------

John Ross	"
-----------	---

Keith Goldman	
---------------	--

LANCE Hemsarth
Joe CONTI

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 10/18/2017 10:06:08 PM
To: Joseph Conti [jconti@hartz.com]
CC: Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Harty, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Harty, Thomas]
Subject: TCVP meeting notes
Attachments: sign in sheet 10.10.17 epa call with hartz.pdf; Notes 10.10.17 telecom with hartz_revised.docx

Hi Joe,

Please see attached for the meeting notes and sign-in sheet from the 10/10/17 teleconference. Take a look and let us know if we mischaracterized anything.

By the way, I am about to go on temporary reassignment in another part of the agency for 4 months. Tom Harty (copied) will manage TCVP for me while I'm away. I will continue to work with Tom in the near future to ensure a smooth transition.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]
Sent: Tuesday, October 10, 2017 4:05 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>
Subject: TCVP Hartz Attendees

Yasushi Takeda
Keith Goldman
Lance Hemsarh
Joe Conti
Ken Prezpaldo

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The Hartz Mountain Corporation

Notes: 10/10/17 EPA Teleconference with Hartz Mountain Corporation (HMC) to Discuss TCVP Data Development

Attendees:

Hartz: Jeff Driver, John Ross, Joe Conti, Lance Hemsarh, Ken Prezpado, Keith Goldman, Yasushi Takeda

EPA: Neil Anderson, Melissa Grable, Khue Nguyen

Discussion:

EPA referenced HED's comments on Hartz's data development plan, which were sent on October 5, 2017. EPA stated that it was only interested in the *in vivo* kinetic study proposed by Hartz and a torsion study with TCVP pet collars, as expressed in the comments. EPA wanted to focus on these two components in order to move the discussions forward. The wipe and weigh study might underestimate the amount of available residue because the test strips are only wiped weekly, and then left to hang in a fume hood in between sampling. The mass-balance limitations would be mostly addressed by the *in vivo* kinetic study and additional discussion with respect to mass balance were not productive, since EPA did not intend to change its residential exposure risk assessment SOP.

Hartz agreed to conduct the *in vivo* kinetic study as recommended by HED, but thought the transferable residue component was important to incorporate into the *in vivo* kinetic study. Hartz stated it intended to scrap plans for the wipe and weigh study. Hartz also disagreed with the need for a torsion study because it thought such a study lacked scientific merit and does not capture exposure in the real world.

EPA stated that even though the torsion study captures the worst case scenario, the information provided by a torsion study (ratio of liquid vs. dust and the composition of the dust) was still a high priority; EPA thought the proposals submitted so far by HMC did not adequately provide a viable alternative for the torsion study.

Hartz thought EPA should treat the residues from TCVP collars as liquid in risk assessment. Hartz referenced PowerPoint slides sent to EPA on October 9, 2017, and noted that when TCVP pet collars were activated, the material that is released is a mixture of DCA and TCVP, which appears as a white pasty film. The TCVP appears as small crystals that are mixed with liquid DCA. The resulting pasty film is mobile like a liquid and moves across the body of the animal via sebum.

EPA noted that an existing statement on the label for registration number 2596-84 referenced a white powder that would appear in the package, and this statement was contrary to Hartz' assertions that the TCVP and DCA mixture was a liquid. Hartz offered to revise its TCVP label for registration number 2596-84, but noted there was an existing label amendment with EPA in RD where CA-required language was being added, and this could complicate the label review. EPA did not think amending this label would address the key question of the liquid vs. solid composition of the TCVP pet collars.

Hartz stated that the existing efficacy database formed a good basis for why EPA should treat TCVP and DCA residues from pet collars as a liquid rather than dust. EPA noted there were a number of efficacy studies in the database, including data from the 70s, but requested that Hartz provide specific studies, or sections of studies, as examples, rather than refer to the entire database, in order to facilitate EPA's review. Hartz stated it would submit specific example(s) from efficacy studies and further relevant

information as part of a white paper; Hartz estimates this would be submitted to EPA by October 20, 2017.

Hartz thought there was a way to modify the kinetic study in order to get the same information that would be generated from a torsion study (*i.e.*, ratio of liquid vs. dust and the composition of the dust). Modifying the kinetic study in this manner would enable EPA to gauge exposure in a more realistic manner. Hartz will discuss this possibility with their contract lab in South Africa and see if this is feasible. Hartz will update EPA on the feasibility of a modified kinetic study by October 27, 2017.

Follow up items:

- 1) Hartz will submit white paper to EPA by October 20, 2017, with additional information to verify the liquid state of the TCVP+DCA mixture, and relevant example(s) from the efficacy database.
- 2) Hartz will consult with their contract lab to discuss the feasibility of adding a new component to the *in vivo* kinetic study to address the liquid vs. dust ratio question. They will provide something to EPA by October 27, 2017.
- 3) Hartz will also update EPA on an estimated date for submission of a revised protocol for the *in vivo* kinetic study by October 27, 2017.

10/10/17: TCV: EPA call with Hartz

[illegible]

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 8/10/2017 9:47:02 PM
To: Joseph Conti [jconti@hartz.com]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Lowe, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ed25a8b48b1425a803ec6bbbe1e2590-Kelly M Lowe]; Britton, Wade [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c4124ab767b4c96b4b436bd02bccfbb-Wade T Britton]; Metzger, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=655bc1c05459419d8bb3ba9a16568c3f-Michael S. Metzger]; Drew, Danette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a99dc94fd974fb6a26f9e35829f881c-Danette Drew]; Rickard, Kristin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=925cb954711f47a3a3f44886f09ab44f-RURY, KRISTIN]
Subject: notes from TCVP discussion
Attachments: TCVP.notes from 8.7.17 teleconference with hartz v2.hed edits.docx; signin sheet 8.7.17 teleconference with hartz.pdf

Hi Joe,

Attached are the notes and sign in sheet from Monday's discussion for TCVP. Please review and let me know if we have mischaracterized anything.

Also, as discussed on the phone this afternoon, here are some possible times for a follow up teleconference:

Mon 8/21, 1-2 pm

Tues 8/22, 11 am-12 pm

Wed 8/23 11 am-12 pm; or 3-4 pm

Call in info for the teleconference:

Personal Matters / Ex. 6

Folks attending from our end: Melissa Grable (PRD), Neil Anderson (PRD), Wade Britton (HED), Kelly Lowe (HED), Kristen Rickard (HED).

I will be out of the office from 8/17 to 8/25. **Please be sure to copy Neil and Melissa on all TCVP correspondence.** Melissa can lead the follow up teleconference in my absence.

If we receive Hartz' protocol by the 16th next week (as you indicated), we will try to look at it as soon as possible in order to have a more productive discussion the week of the 21st.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA

703-347-0248

Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]

Sent: Monday, August 07, 2017 11:27 AM

To: Nguyen, Khue <Nguyen.Khue@epa.gov>

Cc: Dr. Jeffrey Driver **Personal Matters / Ex. 6**; John Ross <jhross@surewest.net>; Lance Hemsarth <lhemsarth@hartz.com>; Keith Goldman <kgoldman@hartz.com>; Yasushi Takeda <ytakeda@hartz.com>

Subject: Proposal/Time Lines

Attached is a proposal and timeline for discussion today. We understand that EPA has requested the meeting to comment on our July 18 submission and the attached testing and timelines may be altered based on our call.

Joe

This e-mail contains confidential and privileged information. If you think you received this e-mail in error, please advise sender by return e-mail, and then delete this e-mail message immediately.

The Hartz Mountain Corporation

8/7/17: TCVP teleconference with Hartz—discuss data development proposal

Name	Organization	Email
Khue Nguyen	PRD/OPP	Nguyen.khue@epa.gov
Joe Landi	Hart 2	jlandi@hart2.com
Jeff Arner	Hart 2	
Lance Hunsarth	Hart 2	
Tolan Pross	Hart 2	
Donette Drew	HED/OPP	
Colwell Cook	BEMD	cook.colwell@epa.gov
Nick Anderson	PRD	ANDERSON, Nick@epa.gov
Melissa Pross	PRD	gracie.melissa@epa.gov
Kelly Love	HEB	
Don Atwood	BEMD	
Krista Rickard	HEB	

TCVP: notes from teleconference with Hartz—8/7/17

EPA and Hartz discussed Hartz's 7/18/17 data development proposal and EPA's recent comments sent on the morning of 8/7/17. Hartz indicated that it would need more time to review EPA's comments, but had some initial thoughts.

With respect Hartz's proposal that contact time/duration of young children measured by the National Exposure Research Laboratory (NERL) be used in pet exposure calculations, Hartz acknowledged the limitations with respect to the Beamer et al., 2008 and Au Yeung et al., 2007 studies, but thought those limitations could be remedied with more information on the data used in the studies. The registrant recommended that EPA reconsider these studies as part of a weight of evidence approach and an area of refinement. EPA believes further discussion on this issue is not useful. Revisions of contact time/number of contacts for children as presented by Hartz is not supportable, and cannot be made supportable with any available information.

With respect to use of biomonitoring data from the Davis, 2008 study, Hartz disagreed with EPA's stance on this topic. PBPK modeling can be done with TCVP, and the CFR doesn't exclude the use of biomonitoring data. Hartz wanted to follow up on this and figure out how to explore this option, possibly by generating a model of the kinetics. EPA's position is that the human studies review board (HSRB) report on the 2008 Davis study indicates that biomonitoring data cannot be used. This issue has been discussed repeatedly, and further discussion or exploration will not change this conclusion. Further discussion on this topic is not useful.

The short-term, *de novo* data development effort proposed by Hartz to study the rate of loss of TCVP from collars under actual use conditions was discussed. EPA thought the short-term study proposed could potentially refine risk estimates. Release rates during the first 30 days is the parameter of importance to EPA. While Hartz may choose to run the study for whatever time period they desire, EPA requests that the results of the first 30 days be submitted formally to the agency after that portion of the study is concluded.

Hartz stated that it was not committing to conduct a study to evaluate the weight percentage of TCVP and other components from TCVP collars following torsion/mechanical stress. It had recently received the protocol from Bayer for this study and was concerned about the way the study was conducted, and in particular the extreme conditions to which the pet collars were exposed, which is not indicative of typical use. Hartz was concerned about the applicability of this study for their collar. Hartz stated it would need to talk to Bayer before committing to conduct this study.

EPA believes that a study to determine the relative percentage of TCVP present in dust vs. liquid form could be very useful in refining risk estimates, and that the torsion/mechanical stress study, or a similar study, is the best option for estimating the proportion and composition of the dust collected. EPA will make reasonable assumptions about the relative proportions of dust/liquid near the collar and over the rest of the treated pets' bodies in its risk estimates. But in the absence of Hartz being amenable to completing the torsion/mechanical stress study, EPA's position is that it will move forward using a range of assumptions about this ratio as in previous assessments.

In general, out of all the options being explored, Hartz was most in favor of attempting to determine a transfer coefficient for the TCVP collar. EPA noted that while a transfer coefficient study may provide useful information for assessing TCVP exposures and risks, the extended time frame required for completion of this type of study is not consistent with the Agency's need to address currently identified risk concerns. EPA notes that the need for this study was previously discussed with the registrant over the past several years, but no study has been initiated. A transfer coefficient study would give information on how much TCVP is released from the collar, but will not provide information on if the TCVP released is liquid or solid and the proportion of each, which was a key uncertainty in the current risk assessment.

Hartz asked EPA whether/how these data development discussions would influence the release of the PID currently slated for September 2017. EPA was willing to roll back the timeline for decision-making for TCVP, provided that Hartz moves forward with a short-term study (30 days) to examine the release rate of TCVP from pet collars and conduct the TCVP torsion/mechanical stress study (or a similar study). EPA prioritized the following information: the rate of release of TCVP, the % solid released, and the composition of the solid. EPA believes the timeframe for completing these studies should be relatively short, as there is no complicated science involved. Completion of this work by the end of calendar year 2017 is reasonable.

EPA is not willing to wait a long time for data in order to move forward with decision-making. It will not revisit existing SOPs. TCVP has had multiple risk assessments, multiple public comment periods, and EPA first identified the question about liquid vs. dust composition a couple years ago in discussions with all TCVP technical registrants. The information submitted to date has not addressed this uncertainty. EPA also needs to respond to NRDC's petition.

EPA is willing to wait for short term data, but it needs firm agreement for short term data development from Hartz and submission of protocols. Hartz said it would review Bayer's protocol, consult with Bayer, think about the options discussed, and get back to EPA within a week or so. Another teleconference call was discussed, possibly around August 16th, before any protocol submission. Hartz will get back to EPA on the timing of its response by the end of 8/8/17.

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 7/11/2017 9:54:40 PM
To: Joseph Conti [jconti@hartz.com]; Dr. Jeffrey Driver [Personal Matters / Ex. 6]; John Ross [jhross@surewest.net]
CC: Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]
Subject: RE: Agenda and Slides
Attachments: sign in sheet 7.11.17 telecon with hartz.pdf

Hi all,

Thanks for being on the phone with us this afternoon. Attached is the sign-in sheet for the teleconference. While I am away on vacation during the next two weeks, please make sure to copy the following folks on all correspondence, including the submission of any open lit data:

Melissa Grable: grable.melissa@epa.gov (703-308-3953)
Neil Anderson: Anderson.neil@epa.gov (703-308-8187)

I'm working on gathering notes from the teleconference, and will send them tomorrow.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Joseph Conti [mailto:jconti@hartz.com]
Sent: Tuesday, July 11, 2017 1:49 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>; Dr. Jeffrey Driver [Personal Matters / Ex. 6]; John Ross <jhross@surewest.net>
Subject: Agenda and Slides

Please find agenda for our discussion this afternoon. EPA had proposed the meeting, so we have left the opening statements and purpose for the Agency followed by our discussion. The attached slides will be used as a supplement to the Hartz discussion.

Agenda

1. Introductions
2. EPA meeting purpose and position
3. Discussion by Hartz
4. Steps Forward

We look forward to the opportunity and discussion,

Joe Conti
Sr. Director Regulatory & Quality
Hartz Mountain Corporation

This e-mail contains confidential and privileged information. If you think you received this e-mail in error, please advise sender by return e-mail, and then delete this e-mail message immediately.

The Hartz Mountain Corporation

7/10/17: TCVP—teleconference with Hartz

Name	Organization	Email
Khue Nguyen	PRD/OPP	Nguyen.khue@epa.gov
Joe Lando	Hart 2	ilando@hart2.com via phone
Jeffrey Davis	Hart 2	via phone
John D. Parris	Hart 2	via phone
Melissa Grobie	EPA/PRD	grobie.melissa@epa.gov
Steve Smeadman	EPA/BEAD/ETB	smeadman.steph@epa.gov
Don Adams	EPA/BEAD/BA B	adams.donald@epa.gov
Clayton Myers	EPA/BEAD/BA B	myers.clayton@epa.gov
Alfred Brithan	EPA/HEO	brithan.alfred@epa.gov
Bill Smith	EPA/PRD	smith.charles@epa.gov
Colwell Paul	EPA/BEAD/	colwell.paul@epa.gov
Patricia Biggio	EPA/PRD	biggio.patricia@epa.gov
Neil Anderson	PRD	Anderson.Neil@epa.gov
Michael Metzger	HKS	metzger.michael@epa.gov
Linda Yang	HEIS (on phone)	

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 7/6/2017 5:25:44 PM
To: Doug Spilker [doug.spilker@bayer.com]
CC: Robert Zolynas [robert.zolynas@bayer.com]; Anderson, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8996b61c04ce4e5cb9e35b323ee5e824-Neil G. Anderson]; Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Biggio, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a9a640a9a2941c5a9be1c4967e71718-Biggio, Pat]
Subject: RE: TCVP Follow-up
Attachments: tcvp 7.6.17 telecon signin sheet.pdf

Hi Doug,

Thanks for chatting with us. We thought it was a good conversation. Attached is the attendance sheet for the teleconference.

In case you can't read my chicken scratch handwriting, the attendees from EPA are:

Yu-Ting Guilaran
Charles "Billy" Smith
Neil Anderson
Melissa Grable
Patricia Biggio
And myself

As discussed, we look forward to receiving the memorandum addressing the 10X SF which is intended to be posted to the TCVP reg review docket and a separate request for voluntary cancellation of the pet collar products. EPA is interested in additional information on the livestock (poultry, cattle, swine) uses of TCVP and we can get together to discuss those uses in the near future. We already sent some questions about these uses to USDA, so it might be possible to coordinate with USDA on this.

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
Nguyen.khue@epa.gov

From: Doug Spilker [mailto:doug.spilker@bayer.com]
Sent: Thursday, July 06, 2017 12:55 PM
To: Nguyen, Khue <Nguyen.Khue@epa.gov>
Cc: Robert Zolynas <robert.zolynas@bayer.com>
Subject: TCVP Follow-up

Hi Khue,
Thanks again for setting up the teleconference and getting the right people there. I thought it went well.

One of the action items from the call was for me to check to be sure that we did not have any other TCVP-containing pet products besides the two pet collars (EPA Reg. Nos. 11556-164 and -165).

I can confirm that the above listed are the only TCVP-containing pet products registered by Bayer.

Best regards,

Doug

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs

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7/6/17: TCVP—teleconference with Bayer

Name	Organization	Email
Khue Nguyen	PRD/OPP	Nguyen.khue@epa.gov
Dan Sifferth	Boyle	
Robert Sifferth	"	
Patricia Bigg	PRD/OPP	bigg.p@epa.gov
Yu-Ting Guile	PRD	yu-ting.guile@epa.gov
Billy Smith	PRD	smith.b@epa.gov
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Nelissa Guile	PRD	guile.n@epa.gov

Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 8/1/2017 8:32:32 PM
To: Grable, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=017278065a7c4cd68f85ecaff5596788-Grable, Melissa]; Keller, Kaitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a6b15adfd745c6ada1c121dec27ac4-Keller, Kai]
CC: Biggio, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a9a640a9a2941c5a9be1c4967e71718-Biggio, Pat]
Subject: TCVP: draft slides for program review
Attachments: august draft program review slides.TCVP.pptx

Draft slides for TCVP for program review are in the attached. Let me know if you have edits. The telecom with Hartz is on 8/7, so will need to modify slides depending on how meeting goes

Khue Nguyen
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Message

From: Nguyen, Khue [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53463F4F956D4772A6ADA2F68DEBFCB8-NGUYEN, KHUE]
Sent: 10/19/2017 2:10:44 PM
To: Baldwin, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=690cd5f35a844011a4014855e4cec1c3-Mbaldwin]; Biscoe, Melanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d000e3cd8b8469e831b7c06f6418739-Melanie Biscoe]
Subject: TCVP meetings
Attachments: Notes 10.10.17 telecom with hartz_revised.docx; Meeting notes from meeting with Hartz_08_29_17_revised.docx; TCVP.notes from 8.7.17 teleconference.docx; TCVP.epa meeting minutes with hartz edits 7.27.17.docx; TCVP notes from 7.11.17 teleconference_post hed edits.docx

These notes basically document the progression of the data development discussions for the past 3 or so months

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TCVP Follow-up Data Development Discussion with Hartz – August 24, 2017
3:00 – 4:00 p.m.

Meeting Attendees:

EPA:

Wade Britton, HED
Jeff Dawson, HED
Kelly Lowe, HED
Kristin Rickard, HED
Laura Bacon, HED
Melissa Grable, PRD
Patricia Biggio, PRD

On-phone:

Jeff Driver
John Ross
Lance Hemsarh
Keith Goldman
Joe Conti

Meeting Notes:

Two draft protocols were submitted by Hartz for EPA's initial impressions:

- 1) First draft protocol- GLP Wipe and Weigh Protocol for the HUG Flea and Tick Collar
- 2) Second draft protocol- Kinetic Study of the Release of TCVP from a Collar Formulation on Dogs

EPA asked for clarification between these protocols because the two protocols seemed to be similar and addressing the same question.

Hartz stated that the first draft protocol provided (for the Wipe and Weigh Study), in combination with analysis of existing data (bloom data from 1980), could be done in-house and quickly, and this study is to address the liquid vs. solid ratio question. The study may also be used to address the hybrid transfer coefficient (TC). The protocol for the second study is to address the rate of release and is an *in vivo* study. This study will address the amount released over time and the amount still available in the collar. Hartz stated that 60% is released and 40% is left in the collar. Hartz believes that the *in vivo* study will confirm the 1980 bloom data.

Just prior to the meeting Hartz provided two photos of samples, and stated that this was to help address the liquid vs. solid question. The photos were of samples created in the lab, which consisted of the active ingredient (TCVP) in a solid form combined with the liquid plasticizer. This combination creates a paste dispersion or a viscous liquid. Hartz responded that the collar is made up of the two substances in a 1:2 ratio (solid:liquid) on a nominal basis. Hartz stated that this ratio does not change.

EPA asked if TCVP is always released as a solid. Hartz replied that yes, it is always a solid, but not 100% solid, because the two compounds are "intimately" intertwined, and both the liquid and solid are released from the collar simultaneously. The physical character is a crystalline material bonded with a liquid. Based on this discussion, EPA stated that it would be interesting to know which is the most appropriate TC and why. Hartz responded that it will either be a liquid or a liquid hybrid.

EPA stated that it was unclear from reading the Wipe and Weigh protocol that Hartz would be analyzing for both the solid TCVP and the liquid plasticizer. Hartz stated that they would be providing another protocol with the chemical analysis, since the chemical analysis for both protocols will be the same.

EPA also asked about distribution of the product across the animal. Hartz replied that the liquid aspect of what is released from the collar, in combination with the oils in the dog's coat, help to facilitate the movement the product across the dog. They noted that they have efficacy data to show that fleas and ticks are controlled across the animal. If the product was not completely covering the animal, there would be evidence of fleas and ticks on parts of the animal where the product had not yet reached, which is not what was shown by the efficacy data.

Hartz indicated that the data from these studies will be mostly confirmatory to address and confirm the form and relative amounts of chemical released.

EPA also asked if Hartz was planning on doing a mannequin hand study to address the TC. Hartz said that they were not planning to, but that fur clippings might also address this question. They said that they would consider this and get back to EPA.

Hartz asked if EPA wanted cats included in the *in vivo* study. If so, they would reduce the number of animals tested from 6 to 4 within each group. Hartz raised the issue of higher exposure with a smaller sized pet. EPA stated that it would prefer a greater number of animals tested, even if that meant only one species was tested. EPA clarified that they would be fine with just the dog study, but that Hartz could decide to include cats. EPA further noted that according to the protocol, the study length is 210 days; however, the Agency has previously stated, and again stated, that it would prefer a month long study. If Hartz chooses to conduct the study for the full 210 days, EPA expects to receive a report for the first 30 days of the study, and the protocol should be amended to include the report at 30 days.

EPA indicated that the protocols needed to be clearer in terms of what the end result will be and what questions they are meant to answer. EPA suggested that something be submitted to summarize the protocols being proposed and the information that will be provided. Hartz stated that they would provide a white paper with the research questions and what they are trying to address, as well as the amended first protocol (Wipe and Weigh) and the analytical protocol no later than September 6th. They will also provide an update on the availability of the *in vivo* protocol at that time.

EPA stated that it would not be providing the Proposed Interim Decision (PID) at the end of September, but it instead would provide an update stating that additional data was being generated by the registrant to address uncertainties identified in the risk assessment. Hartz stated that they wanted to review the update before it was made public. In addition, they wanted to ensure that the supplier was identified as the Task Force and not specifically Hartz. EPA stated that it would check on these two items and respond back to Hartz.

Next Steps:

- Hartz will provide a white paper to EPA that addresses the existing and proposed data.
 - Information addressed in the white paper should include what Hartz believes on the following topics:
 - What question(s) each study will address, and if data may be considered refinement, confirmation or new information.

- How the proposed data will be considered within the context of existing data (*e.g.*, bloom study, EPA's residential SOPs).
- After receiving the updated draft protocols, EPA will consider these in tandem with the white paper and additional information from Hartz, and work with Hartz to determine a schedule for study initiation and submission.

Notes: 10/10/17 EPA Teleconference with Hartz Mountain Corporation (HMC) to Discuss TCVP Data Development

Attendees:

Hartz: Jeff Driver, John Ross, Joe Conti, Lance Hemsarh, Ken Prezpado, Keith Goldman, Yasushi Takeda

EPA: Neil Anderson, Melissa Grable, Khue Nguyen

Discussion:

EPA referenced HED's comments on Hartz's data development plan, which were sent on October 5, 2017. EPA stated that it was only interested in the *in vivo* kinetic study proposed by Hartz and a torsion study with TCVP pet collars, as expressed in the comments. EPA wanted to focus on these two components in order to move the discussions forward. The wipe and weigh study might underestimate the amount of available residue because the test strips are only wiped weekly, and then left to hang in a fume hood in between sampling. The mass-balance limitations would be mostly addressed by the *in vivo* kinetic study and additional discussion with respect to mass balance were not productive, since EPA did not intend to change its residential exposure risk assessment SOP.

Hartz agreed to conduct the *in vivo* kinetic study as recommended by HED, but thought the transferable residue component was important to incorporate into the *in vivo* kinetic study. Hartz stated it intended to scrap plans for the wipe and weigh study. Hartz also disagreed with the need for a torsion study because it thought such a study lacked scientific merit and does not capture exposure in the real world.

EPA stated that even though the torsion study captures the worst case scenario, the information provided by a torsion study (ratio of liquid vs. dust and the composition of the dust) was still a high priority; EPA thought the proposals submitted so far by HMC did not adequately provide a viable alternative for the torsion study.

Hartz thought EPA should treat the residues from TCVP collars as liquid in risk assessment. Hartz referenced PowerPoint slides sent to EPA on October 9, 2017, and noted that when TCVP pet collars were activated, the material that is released is a mixture of DCA and TCVP, which appears as a white pasty film. The TCVP appears as small crystals that are mixed with liquid DCA. The resulting pasty film is mobile like a liquid and moves across the body of the animal via sebum.

EPA noted that an existing statement on the label for registration number 2596-84 referenced a white powder that would appear in the package, and this statement was contrary to Hartz' assertions that the TCVP and DCA mixture was a liquid. Hartz offered to revise its TCVP label for registration number 2596-84, but noted there was an existing label amendment with EPA in RD where CA-required language was being added, and this could complicate the label review. EPA did not think amending this label would address the key question of the liquid vs. solid composition of the TCVP pet collars.

Hartz stated that the existing efficacy database formed a good basis for why EPA should treat TCVP and DCA residues from pet collars as a liquid rather than dust. EPA noted there were a number of efficacy studies in the database, including data from the 70s, but requested that Hartz provide specific studies, or sections of studies, as examples, rather than refer to the entire database, in order to facilitate EPA's review. Hartz stated it would submit specific example(s) from efficacy studies and further relevant

information as part of a white paper; Hartz estimates this would be submitted to EPA by October 20, 2017.

Hartz thought there was a way to modify the kinetic study in order to get the same information that would be generated from a torsion study (*i.e.*, ratio of liquid vs. dust and the composition of the dust). Modifying the kinetic study in this manner would enable EPA to gauge exposure in a more realistic manner. Hartz will discuss this possibility with their contract lab in South Africa and see if this is feasible. Hartz will update EPA on the feasibility of a modified kinetic study by October 27, 2017.

Follow up items:

- 1) Hartz will submit white paper to EPA by October 20, 2017, with additional information to verify the liquid state of the TCVP+DCA mixture, and relevant example(s) from the efficacy database.
- 2) Hartz will consult with their contract lab to discuss the feasibility of adding a new component to the *in vivo* kinetic study to address the liquid vs. dust ratio question. They will provide something to EPA by October 27, 2017.
- 3) Hartz will also update EPA on an estimated date for submission of a revised protocol for the *in vivo* kinetic study by October 27, 2017.

TCVP: notes and action items for 7/11/17 teleconference with Hartz

EPA indicated that it intended to publish the proposed interim registration review decision for TCVP in September 2017. The focus of the proposed decision is the pet uses. EPA is awaiting a final decision on the use of the 10X FQPA database uncertainty factor for all the organophosphates, and so the agency intends to address dietary, occupational, and eco risks at a later date.

Hartz thought implementing risk mitigation for pet uses was premature and thought there was room for refinement in EPA's current risk assessment. Hartz put forward several proposals for refinement via PowerPoint slides, including the use of adult biomonitoring data for children, use of information on timed contact with pets and frequency of contact with pets, and refining the mass balance estimates which is currently too conservative. EPA pointed Hartz to its most recent "response to comments" document for the occupational and residential assessment, where most of these comments were already addressed. EPA did not have a chance to examine the NERL data cited in Hartz' slides relating to contact with treated pets (i.e., number and duration of pet contacts), but indicated that Hartz should submit these studies as soon as possible, including any raw data.

EPA indicated that it was interested in data which might help refine the number and duration of pet contact inputs. EPA discussed recent registrant data for pet collars that sought to determine what fraction of the collar was liquid and what fraction was solid. Having access to similar data for TCVP could potentially impact the risk picture. Hartz was open to working with EPA on developing additional data, but was concerned about the September deadline.

EPA's timeline is spurred by its obligation to respond to NRDC's petition for the pet uses. EPA indicated that Hartz should submit a solid proposal describing what data will be developed and a timeline for the submission of this data in the next few weeks. EPA does not have flexibility to extend the September deadline without more concrete information. Hartz said it needed to discuss internally. Hartz agreed to submit a letter of intent with a proposed timeline for the key elements discussed by Tuesday 7/18.

Action items from teleconference:

- 1) Hartz will submit a letter of intent with a proposed schedule for submission of key elements discussed (including raw data for the NERL studies, a data development proposal, and a schedule for data development) by Tuesday 7/18/17
- 2) Hartz will submit to EPA the NERL data cited in its slides (with raw data) for EPA's review (NERL studies received post-meeting, awaiting raw data)
- 3) Hartz will submit a data development proposal and a schedule for data development (date not yet determined)
- 4) EPA will send contact information for Neil and Melissa, who are the alternate contacts while Khue is on vacation (completed post-meeting)

TCVP: EPA notes and action items for 7/11/17 teleconference with Hartz including Hartz revisions

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Hartz thought implementing risk mitigation for pet uses was premature and believes there was room for refinement in EPA's current risk assessment. Hartz put forward several proposals for refinement via PowerPoint slides, including the use of adult biomonitoring data for children, use of information on timed contact with pets and frequency of contact with pets, and refinements based on mass balance considerations. EPA pointed Hartz to its most recent "response to comments" document for the occupational and residential assessment, where most of these comments were already addressed. Hartz indicated that in their view, the proposed refinements have not been adequately addressed by EPA's "response to comments" and requested further consideration, *e.g.*, utilization of open literature publications, and associated data regarding pet contact duration and frequency, mass balance consideration, and use of adult biomonitoring data, that included participants providing glove dosimetry data currently being used by EPA. EPA did not have a chance to examine the NERL data cited in Hartz' slides relating to contact with treated pets (i.e., number and duration of pet contacts), but indicated that Hartz should submit these studies as soon as possible, including any raw data for review.

EPA indicated that it was interested in data which might help refine the number and duration of pet contact inputs. EPA discussed recent registrant data for pet collars that sought to determine what fraction of the collar was liquid and what fraction was solid. Having access to similar data for TCVP could potentially impact the risk picture. Hartz was open to working with EPA on developing additional data, but was concerned about the September deadline.

EPA's timeline is spurred by its obligation to respond to NRDC's petition for the pet uses. EPA indicated that Hartz should submit a solid proposal describing what data will be developed and a timeline for the submission of this data in the next few weeks. EPA does not have flexibility to extend the September deadline without more concrete information. Hartz said it needed to discuss internally. Hartz agreed to submit a letter of intent with a proposed timeline for the key elements discussed by Tuesday 7/18.

Action items from teleconference:

1. Hartz agreed to submit a letter of intent with a proposed schedule for submission of key elements discussed (including raw data for the NERL studies if available, a data development proposal, and a schedule for data development) by Tuesday 7/18/17
2. Hartz will submit to EPA the NERL data cited in its slides (with raw data) for EPA's review (NERL studies received post-meeting, awaiting raw data)
3. Hartz will submit a data development proposal and a schedule for data development (date not yet determined)
4. EPA will send contact information for Neil and Melissa, who are the alternate contacts while Khue is on vacation (completed post-meeting)

TCVP: notes from teleconference with Hartz—8/7/17

EPA and Hartz discussed Hartz' 7/18/17 data development proposal and EPA's recent comments sent on the morning of 8/7/17. Hartz indicated that it would need more time to review EPA's comments, but had some initial thoughts. With respect to item 1 (Hartz' proposal that contact time/duration of young children measured by NERL be used in pet exposure calculations), Hartz acknowledged the limitations with respect to the Beamer et al 2008 and Au Yeung et al 2007 studies, but thought those limitations could be remedied with more information on the data used in the studies. EPA should consider these studies as part of a weight of evidence and an area of refinement.

With respect to item 2 (use of biomonitoring data from the Davis 2008 study), Hartz disagrees with EPA's current stance on this. PBPK modeling can be done with TCVP and the CFR doesn't exclude the use of biomonitoring data. Hartz wanted to follow up on this and figure out how to explore this option, possibly by generating a model of the kinetics. EPA said the data would need to go through the human studies review board (HSRB), which previously identified issues with recruiting for such studies, and EPA had poor reception of similar data in the past. EPA was not interested in exploring this option.

With respect to item 3 (mass balance issue with EPA's current assessment methodology for pet collars), Hartz thought there were additional aspects to consider and wanted to follow up further. Hartz thought reasonable assumptions could be made on residue amounts on the individual or in the environment. EPA reiterated its belief that the mass balance issue would be addressed with the additional data on the release rate of TCVP and the mechanical stress/torsion study that was being proposed.

With respect to item 4 (proposed data development), Hartz stated that it was not committing to conduct a study to evaluate the weight percentage of TCVP and other components from TCVP collars following torsion/mechanical stress. It had recently received the protocol from Bayer for this study and was concerned about the science. The study does not meet the needs of Hartz' pet collar product—torsion is an extreme condition that pet collars would not likely to be exposed to. Hartz stated it would need to talk to Bayer before committing to conduct this study.

In general, out of all the options being explored, Hartz was in favor of item 3 (addressing the mass balance issue) by attempting to determine a transfer coefficient for the TCVP collar. EPA thinks this option was associated with too much uncertainty and would involve a longer-term endeavor. This option would give info on how much TCVP is released from the collar, but won't give info on if the TCVP released is liquid or solid and the proportion of each, which was a key uncertainty in risk assessment.

EPA was interested in how much TCVP can come off a collar in a day's time. The mass balance issue would be addressed as a consequence of the torsion study, but it was not the key item to focus on. EPA suggests a shorter timeframe for a study (30 days) instead of a longer study. The key is what is being released and whether it was liquid or solid. If Hartz disagreed with Bayer's approach, it should come up with its own proposal for measuring how much solid will be released from the TCVP collar, and determine the composition of the solid.

Hartz asked EPA whether/how these data development discussions would influence the release of the PID currently slated for September 2017. EPA was willing to roll back the timeline for decision-making for TCVP, provided that Hartz move forward with a short-term study (30 days) to examine the release

rate of TCVP from pet collars and conduct the TCVP torsion study. EPA prioritized the following info: the rate of release of TCVP, the % solid released, and the composition of the solid.

EPA was not willing to wait a long time for data in order to move forward with decision-making. It was not willing to revisit existing SOPs. TCVP has had multiple risk assessments, multiple public comment periods, and EPA first identified the problem with the liquid vs. dust composition question a couple years ago in discussions with all TCVP technical registrants. The information submitted through info requests did not address this uncertainty. EPA also needed to respond to NRDC's petition.

EPA will wait for short-term data, but it needed firm agreement from Hartz. Hartz said it would review Bayer's protocol, consult with Bayer, think about the options discussed, and get back to EPA. Hartz would need at least a week. Another teleconference call was discussed, possibly around August 16th, before any protocol submission. Hartz will get back to EPA on the timing of its response by the end of 8/8/17.